UNIVERSIDAD AUTONOMA DE MADRID

PhD Thesis

Functioning in Bipolar Disorders: A multi-informant approach.

PhD Student: Carolina Carvalho de Ávila e Pereira

Supervisors: Dr. José Luis Ayuso Mateos (UAM, Spain)
Dr. Alarcos Cieza (LMU, Germany)

Department of Psychiatry,
School of Medicine
Universidad Autónoma de Madrid

Carolina Carvalho de Ávila e Pereira
June 2010

Acknowledgments

I would like to start this document by acknowledging all the people that made it this work possible, and direct them some words in their own languages:

En primer lugar, a los Directores de esta tesis: Al Doctor. José Luis Ayuso-Mateos, con quien he tenido la oportunidad de trabajar a lo largo de los últimos tres años, por haber confiado y mí y disponibilizado todos los recursos para que esta tesis se tornase realidad. A la Doctora Alarcos Cieza, por todos los aprendizajes que me proporcionó y toda la fuerza que siempre me fue dando desde Múnich.

A todos mis compañeros, pasados y presentes, del Grupo Multidisciplinar de Investigación en Trastornos Afectivos: Antonio Veronese, Celia Anaya, Hesham Gadelrab, Itziar Leal, Mar Rivas, María Cabello, Marta Miret, Marta Nieto, Matilde Hernández, Patricia Fernández, Patricia Gimeno y Roberto Nuevo.

To all the MURINET fellows and Principal Investigators I had the opportunity to work and travel with.

An die KollegInnen der ICF Research Branch in München für die angenehme und wertvolle Zusammenarbeit und für die immer „öffene Tür".

À Senhora Doutora Margarida Rangel Henrinques por toda a motivação e ajuda.

A Celia Anaya y a Magdalena Capo, por todas las correcciones de las partes en castellano de esta tesis doctoral.

Aos meus Pais, pelo apoio à distância e por sempre me terem incentivado a ir mais longe, mesmo quando isso implicou fazer as malas e deixar saudades. Também aos meus Avós, pelos mesmos motivos.

Aos meus amigos no Porto, porque sempre me souberam receber de volta e compreender as minhas ausências.

A todos mis amigos en Madrid, por hacerme sentir tan a gusto en esta ciudad e incentivarme a escribir esta tesis.

This work was by the Marie Curie Actions of the Sixth Framework of the European Commission through the Project MURINET – Multidisciplinary Research Network on Health and Disability in Europe (MRTN-CT-2006-035794).

Ao vento

O vento passa a rir, torna a passar,
Em gargalhadas ásperas de demente;
E esta minh'almea trágica e doente
Não sabe se há-de rir, se há-de chorar!

Vento de voz tristonha, voz plangente,
Vento que ris de mim, sempre a troçar,
Vento que ris do mundo e do amar,
A tua voz tortura toda a gente!...

Vale-te mais chorar, meu pobre amigo!
Desabafa essa dor a sós comigo,
E não rias assim!... Ó vento, chora!

Que eu bem conheço, amigo, esse fadário
Do nosso peito ser como um Calvário,
E a gente andar a rir pla vida fora!!...

(Florbela Espanca, Sonetos)

Table of contents

Index of Figures

Index of Tables

List of abbreviations (English)

A&P	Activities and Participation
BAS	Barners Akathesia rating Scale
BC	Breast Cancer
BD:	Bipolar Disorders
BDI	Bipolar Disorder type I
BDII	Bipolar Disorder type II
BF	Body Functions
BI:	Barthel Index
BPRS	Brief Psychiatric rating Scale
BS	Body Structures
CGI	Clinical global Impression
CI	Confidence Intervals
CIHD	Chronic Ischemic Heart Diseases
CWP	Chronic Widespread Pain
D	Depression
DM	Diabetes Mellitus
DPI	Disabled People's International
DSM	Diagnostic and Statistical Manual of Mental Disorders
EF	Environmental Factors
EULAR	European League against Rheumatism
FIM:	Functional Independence Measure
GAF	Global Assessment of Functioning Scale
GAS	Global Assessment Scale
HDRS	Hamilton Depression Rating Scale

ICD: International Classification of Diseases

ICF: International Classification of Functioning, Disability and Health

ICIDH: International Classification of Impairment, Disability and Handicap

LBP Low Back Pain

M Medium

Max Maximum

MHADIE Measuring Health and Disability in Europe

MIN Minimum

MURINET Multidisciplinary Research Network in Health in Disability in Europe

OA: Osteoarthritis

OB Obesity

OMERACT Measures in Rheumatoid Arthritis Clinical Trials

OPD Obstructive Pulmonary Diseases

OTs: Occupational Therapists

PTs: Physical Therapists

QoL: Quality of Life

RA: Rheumatoid Arthritis

SANS Scale for the Assessment of Negative Symptoms

SCID Structured Clinical Interview for DSM-IV

SCWF Stroop Colour Work Interference Test

SD Standard Deviation

SPSS Statistical Package for Social Sciences

ST Stroke

UPIAS Union of Physically Impaired against Segregation

WAIS Wechsler Adult Intelligence Scale

WCST Wisconsin Card Sorting Test

WHA: World Health Assembly

WHO: World Health Organization

WHODAS World Health Organization Disability Assessment Scale

YLD Years lived with Disabilities

YMRS Young Mania Rating Scale

Lista de Abreviaciones (Español)

CIE Clasificación Internacional de Enfermedades

CIF Clasificación Internacional del Funcionamiento, de la Discapacidad y de la Salud

DSM Manual de diagnóstico y estadística de los trastornos mentales

EEUU Estados Unidos

OMS Organización Mundial de la Salud

TB Trastorno Bipolar

Preface

The present work was conducted with a double finality. On the one hand, the objective was to describe functioning in individuals with Bipolar Disorder (BD) according to different perspectives and on the other hand to use these findings to create a tool that will help assessment and data collection with such patients in a universal way and allow the systematization of the information using a comprehensive and up-to-dated classification of health, disability and functioning.

For this reason, and through this document, emphasis is been placed in contributing to the answer of questions such as: what are the most affected areas in individuals with bipolar disorders according to health professionals worldwide? Where do diagnosed individuals with BD find their biggest difficulties to be? What are researchers focusing on regarding this health condition? Secondly, effort was made to use the findings to create, with the collaborations of experts from different world regions, the first version of the International Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2001) Core Sets for Bipolar Disorders. If this Core Set is implemented in clinical or research settings, then research has fulfilled its purpose of contributing to the daily practice and serve the community.

This document is structured in the typical sections: introduction and framework, objectives and hypotheses, methods, results and discussion, and is divided in four different studies: a) a systematic review of the literature, b) a qualitative study using individual interviews, c) an expert survey and finally d) a report on

an international consensus conference where the first version of ICF Core Sets for BD was established.

To meet the requirements for an European Mention in the PhD diploma the present thesis was be written in two european languages, one of them being Spanish (the official language of the University) and the other one English. Concretely, an abstract is provided in Spanish and the Discussion Section is also written entirely in Spanish, while the remaining text is written in English.

Resumen (Español)

Introducción:

El presente trabajo expone la metodología y resultados obtenidos a través de cuatro estudios: una revisión sistemática de la literatura sobre el trastorno bipolar (TB), un estudio cualitativo con individuos que padecen de esa enfermedad, una encuesta ("survey") internacional en que se encuestaron expertos en TB y un proceso de consenso, igualmente con expertos mundiales, en el que se llegó a un consenso sobre cuáles eran las áreas de funcionamiento más afectadas en este trastorno y cuáles las categorías de la Clasificación Internacional del Funcionamiento, de la Discapacidad y de la Salud (CIF) que deberían ser incluidas en los Core Sets de la CIF para TB. En todos los estudios esta misma clasificación fue utilizada como referencia.

Objetivos:

El objetivo de la *revisión sistemática de la literatura* fue identificar y examinar sistemáticamente la frecuencia del uso de los conceptos contenidos en las variables del resultado de estudios de los trastornos bipolares usando la CIF como referencia

El objetivo principal de las *entrevistas cuali*tativas fue identificar los aspectos relevantes y los problemas relacionados con TB según la propia perspectiva del paciente y dentro del marco de la CIF. Los objetivos principales fueron (1) explorar y entender la perspectiva de los pacientes con TB sobre su funcionamiento y su salud usando un acercamiento cualitativo e (2) identificar los conceptos importantes para estos pacientes y que se encuentran relacionados importantes para estos pacientes.

El objetivo de la *encuesta a los expertos* fue el de explorar la perspectiva de expertos sobre problemas relevantes en individuos con TB. Los objetivos específicos fueron (1) identificar los problemas importantes en el funcionamiento para los pacientes con TB y (2) cuantificar estos problemas con la CIF

El objetivo de la *Conferencia de Consenso de los Core Sets de la CIF* fue llegar a un consenso internacional en cuanto a las categorías de la CIF más adecuadas para ser incluidas en los Core Sets de la CIF.

Métodos:

Los estudios originales publicados entre 2000 y 2006 fueron localizados en las bases de datos de MEDLINE® y de PsycINFO y seleccionados según criterios predeterminados. Las variables de resultados fueron incorporados a la CIF.

Los datos sobre la perspectiva individual en el TB fueron recogidos a través de entrevistas con adultos que sufren de TB de tipo I y II. Toda la información recopilada fue traducida a categorías CIF y se calcularon las frecuencias relativas y absolutas de cada una de esas categorías.

La perspectiva de los expertos fue abordada a través de una encuesta online con expertos que trabajan con individuos con TB. La información obtenida a través de las respuestas dadas fue mapeada a categorías CIF y las frecuencias relativas y absolutas de cada una de ellas fueron calculadas.

Para establecer la primera versión de los core sets de la CIF se llevó a cabo un proceso de consenso con expertos mundiales en el que se integraron los datos obtenidos a través de la revisión sistemática de la literatura, las entrevistas cualitativas y la encuesta con expertos. Se presentaron también datos obtenidos en un estudio empírico con pacientes bipolares.

Resultados:

En la *revisión sistemática de la literatura* fueron incluidos finalmente 109 estudios. Los conceptos contenidos en estos estudios fueron ligados a 145 categorías diferentes de ICF. La categoría de la CIF b152 "funciones emocionales" fue la categoría más frecuentemente representada, apareciendo en el 94% de las publicaciones, seguida de b126 "funciones de la personalidad y del temperamento" (73%). Las categorías e110 "productos o sustancias para consumo propio" y e580, "servicios, sistemas y políticas sanitarias" aparecieron en el 68% de los estudios.

Las 'Funciones Corporales' que aparecieron con mayor frecuencia en las *entrevistas cualitativas* fueron b126 'Funciones del temperamento y la personalidad', seguido por b152 'Funciones emocionales' y b130 'Funciones relacionadas con la energía y los impulsos' (67%). Dentro del dominio de la CIF 'Actividades y participación', las categorías d920 'Tiempo libre y ocio' y d770 'Relaciones íntimas' (40%) mostraron las frecuencias relativas más altas. La categoría e310 'Familiares cercanos' (87%) tuvo la frecuencia más alta de aparición en el componente de 'Factores Ambientales', seguida por la categoría e315 'Otros familiares' (66%). En cuanto a las 'Estructuras corporales', ninguna categoría apareció en más de un protocolo.

Un total de 68 participantes de las 6 regiones del mundo de la OMS completó el *cuestionario en línea*. De las 68 respuestas, un total de 2065 conceptos fueron obtenidos. Después de vincular éstos a la CIF, se obtuvieron un total de 107 categorías de la CIF en el segundo nivel de la clasificación.

Las categorías con mayor frecuencia de aparición en el cuestionario fueron e310 "familia cercana" y e580 "servicios, sistemas y políticas sanitarias" (75%

cada una), seguidas por e315 "familia lejana" (72%) y b152 "funciones emocionales" (68%). Del dominio "Estructuras del cuerpo", la categoría más considerada fue s580 "estructura de la glándulas endocrinas". Con respecto a "Actividades y participación", d845 "Obtener, mantener y terminar un trabajo" fue la más seleccionada.

En la *conferencia de consenso* fue definida una primera versión, una breve y otra, comprehensiva, de los core sets para TB. El core set comprehensivo contiene 38 categorías y el breve 19. Los dominios "funciones corporales", "actividades y participación" y "factores ambientales" están representados en ambas versiones de los core sets. Ninguna categoría del dominio "estructuras corporales" fue incluida.

Conclusiones:

La *revisión sistemática* refleja el foco de la investigación de la literatura en TB de estos últimos años. La mayor parte de los estudios realizados se concentran en las funciones del cuerpo más que en actividades y en los dominios de participación. Los estudios experimentales son, sobre todo, farmacológicos, reflejando la necesidad de estudiar intervenciones no-farmacológicas. Además, este estudio demuestra que las variables del resultado usadas en estudios con las personas con TB se pueden, en gran parte, traducir a la CIF.

El uso de *entrevistas semi-estructuradas* permitió que diéramos voz a los pacientes, sin obligarlos a conformarse con categorías predefinidas, y el uso de la CIF sirvió como una herramienta adecuada para identificar y cuantificar la información sobre el funcionamiento del paciente y para superar algunas de las dificultades de los investigadores a la hora de llevar a cabo una investigación cualitativa.

La metodología utilizada en el *cuestionario con expertos* permitió la recogida de datos proveniente de diferentes países, contribuyendo así a superar la limitación de la dificultad de generalización de los resultados obtenidos de diferentes países, lo que se apuntaba frecuentemente como una limitación en diversas investigaciones y en particular en los estudios que utilizan técnicas cualitativas.

Los datos obtenidos a través de los diferentes estudios permitieron la definición de la primera versión de los core sets de la CIF. Sin embargo, es necesario tener en cuenta que los resultados obtenidos a través de cualquier proceso de consenso pueden diferir de grupo a otro, por lo que es importante enfatizar la necesidad de validar y por ello, someter esta primera versión de los core sets a la perspectiva y evaluación de diferentes grupos profesionales y de diferentes países

Introduction

The concept of Functioning

Functioning and disability are core universal human experiences. Across a life span, most individuals will experience some degree of limitations in functioning in relation to acute and/or chronic health conditions and/or with ageing. In this sense, disability is a universal part of the human condition (Bickenbach, Chatterji, Badley, & Ustun, 1999). According to World Health Organization (WHO) estimates, approximately 10 percent of the world's population, or 650 million people, currently live with a physical and/or mental disability. This figure is increasing as a result of population growth, medical advances and lengthening of the ageing process. Malnutrition, war, violence, road traffic, domestic and occupational injuries and other causes often related to poverty also contribute to the increase in the prevalence of disability.

It is therefore not surprising that improving or maintaining functioning and preventing disability is becoming one of the most urgent outcomes from a public health perspective (G. Stucki, Cieza, & Melvin, 2007). Traditional public health outcomes, such as mortality and diagnostic data on morbidity and diseases, are important in their own right. However, they do not adequately capture health outcomes of populations (Ustun, Chatterji, & Konstansjek, 2004).

The recent WHO resolution (WHA58.23) on "Disability, including prevention, management and rehabilitation", adopted in May 2005 by the 58th World Health Assembly, recognized the role and magnitude of disability in society. Consequently, preventative actions, such as encouraging physical activity in order to avoid frailty in old age, are currently being proposed. The United

Nations Convention on the Rights of Persons with Disabilities also draws the attention of governments to the relevance of functioning and disability in society. While the convention does not establish new human rights, it does describe the obligations of states to promote, protect and ensure the rights of persons with disabilities. Moreover, it outlines the many steps that states must take to create an enabling environment, so that persons with disabilities can enjoy equality in society.

Functioning and disability are also key concepts in the practice of clinical medicine (A. Cieza & Stucki, 2004). The management of limitations in functioning complements medical and surgical care throughout the service continuum, from acute to community health-care situation (Gerold Stucki, Stier-Jarmer, Grill, & Melvin, 2005a). In medical disciplines, such as physical medicine and rehabilitation and psychiatry, functioning and disability are fundamental realities that are not only considered for diagnostic purposes, but also for intervention management and evaluation of treatment outcomes (Kennedy, 2003) Thus, the implementation of approaches that describe, assess and evaluate functioning and disability of persons with health conditions in the continuum of care appears to be a priority and presumably will remain so in years to come.

Since 1970s, different conceptual and methodological approaches, such as valuation methods, instruments to assess health status and classifications, have evolved to describe, assess and evaluate functioning and disability (G Stucki et al., 2002). The former, valuation, includes methods derived from economics and decision analyses, such as the standard gamble, the time trade-off, and willingness to pay. These methods have been used in health policy analysis and

in resource allocation and allow for comparisons of the impact of disability and the cost-utility of different treatments. They are, however, rarely applied in clinical medical practice. Instead, the latter, instruments to assess health status and classifications, are already being used in clinical medical practice.

Two good examples of instruments to assess health status that are routinely used in clinical medical practice are the Functional Independence Measure (FIM™) (Keith, Granger, Hamilton, & Sherwin, 1987) and the Barthel Index (BI) (Mahoney & Barthel, 1965). The FIM™ contains 18 items referring to self-care, bowel and bladder continence, mobility and ambulation, communication, social functioning, and cognition. The ten items of the BI refer to similar areas as the FIM™, including feeding, grooming, bathing, dressing, bowel and bladder care, toilet use, ambulation, and transfers. Both of them are internationally used for assessment, intervention management and outcome evaluation in clinical neurorehabilitation.

Bipolar Disorder

Bipolar disorder (BD) is a mood disorder with mania or hypomania as its hallmark (Thomas, 2004). In the current official classifications, Diagnostic and Statistical Manual-IV of the American Psychiatric Association (DSM-IV) (American Psychiatry Association, 1994a) and ICD-10 (Word Health Organization, 1992), at least two subtypes are distinguished. Bipolar type I disorder, the most classic form, is characterized by a succession of manic or mixed states, with depressive episodes. In bipolar type II disorder, depression dominates the course and alternates with hypomania. Current data indicate that bipolar type I disorder involves at least 1% of the worldwide population

(Weissman et al., 1996). If we also take into account the prevalence of bipolar II disorder and bipolar spectrum subtypes (Kupfer, 2005), the prevalence of all BDs could be estimated at more than 3% (Akiskal et al., 2000). BD is a lifelong illness with a high mortality rate. The lifetime risk of suicide attempts ranges from 25 to 50%, and death by suicide occurs in 10–15% of inadequately treated patients (Thomas, 2004). BD is also associated with an enormous economic burden, the largest component of which derives from lost productivity (Wyatt & Henter, 1995). Global burden of disease analysis shows that BD is ranked as the ninth leading cause of burden among all diseases in the age group of 15–44 years. BD accounts for 2.5% of the total disability adjusted years in that age group. It is also the ninth most common cause of years lived with disability (YLD), accounting for 2.5% of total YLDs across all age groups (Word Health, 2001) and for 4.7% of total YLDs in the age group of 15–44 years. Functioning is increasingly being taken into account in assessing the impact of BD on the individual, as well as the effectiveness of treatments. Functioning is a complex concept, since it involves the capacity to work, study, live independently, and engage in recreational activities and interpersonal relationships whereas disability is a difficulty in functioning at the body, person, or societal levels, in one or more life domains, as experienced by an individual with a health condition in interaction with contextual factors. Difficulties in work productivity and problems in functioning have consistently been reported as related to BD in the literature (Dean, Gerner, & Gerner, 2004). Early reports of persistent diminished psychosocial functioning were played down in favor of the view that BD is a periodic illness with little residual deficit (MacQueen, Young, & Joffe, 2001). After the remission of manic or depressive episodes, a recovery to

premorbid function is expected. However, many authors have described significantly poorer social adjustment, even in fully remitted patients (Coryell et al., 1993) (De Lisio et al., 1986) (Perugi, Maremmani, McNair, Cassano, & Akiskal, 1988). This poor functioning, even in treated euthymic patients (that is, in patients currently in a normal mood state), is one of the main factors that explains the high burden of BD patients, and it is consistent with recent studies highlighting the modest impact of available interventions on the functional outcomes of a large proportion of this group (Chisholm, van Ommeren, Ayuso-Mateos, & Saxena, 2005). A number of factors may affect the outcome of BD, such as clinical features (age at onset, frequency of episodes, cycle pattern, rapid cycling, psychotic symptoms, mixed symptoms) (Suppes T, 2000), psychiatric comorbidity (Vieta et al., 2000) and treatment compliance (Colom et al., 2003). The impact of neurocognitive factors has not been well investigated, and probably constitutes a good predictor of functioning (A. Martinez-Aran et al., 2004; Anabel Martinez-Aran et al., 2004). Pharmacological factors may also play a relevant role in the level of functioning of bipolar patients (Endicott, Spitzer, Fleiss, & Cohen, 1976; A. Martinez-Aran, et al., 2004). Moreover, there are studies showing that the problems and difficulties in functioning experienced by patients with BD are closely related to the support provided by different agents and environmental factors, including the family and the community, social services, systems and policies (Hirschfeld, Lewis, & Vornik, 2003; Johnson, Lundstrom, berg-Wistedt, & Mathe, 2003; Morselli, Elgie, & Cesana, 2004; Otto et al., 2004; Perlick, Hohenstein, Clarkin, Kaczynski, & Rosenheck, 2005).

A review of the studies on MEDLINE from 2000 to 2006, using the search criteria "bipolar disorder", "functioning", "disability" and "quality of life", shows that 79 studies have been published in which functioning, disability, and/or quality of life have been investigated in relation to BD. The most widely used measures in these studies were the Global Assessment of Functioning Scale (American Psychiatry Association, 1994b), the Short Form-36 (SF-36) (Ware & Sherbourne, 1992), the Global Assessment Scale (Endicott, et al., 1976), the National Institute of Mental Health Life Chart Methodology (Denicoff et al., 1997) and the Quality of Life Enjoyment and Satisfaction Questionnaire (Endicott, Nee, Harrison, & Blumenthal, 1993). Other measures used in not more than three studies were the World Health Organization Quality of Life Assessment (WHOQOL) (World Health Organization, 1998): development and general psychometric properties," 1998), the European Quality of Life Instrument (Saxena & Orley, 1997) ,Social Adjustment Scale, Lehman's Quality of Life Interview (Lehman, 1983), the Range of Impaired Functioning Toll (Leon et al., 1999) and the Multidimensional Scale of Independent Functioning (Berns, Uzelac, Gonzalez, & Jaeger, 2007; Judith Jaeger, Berns, Loftus, Gonzalez, & Czobor, 2007).

There is, however, little standardization in the use of these instruments, and therefore comparisons among studies are difficult or impossible. In addition, these instruments typically cover only selected aspects of the entire experience associated with BD. It is also important to note that there is no condition-specific instrument for BD; the instruments cited above were not developed to measure the health problems specifically associated with BD. It would, therefore, be valuable for clinical practice and research to have a practical tool covering the

spectrum of symptoms and limitations in functioning of patients with BD, taking into account the environments in which they live. An important basis for the optimal management of DB is an in-depth understanding, systematic consideration and sound measurement of its consequences at different levels. To achieve this goal, we need a comprehensive framework and classification which can serve as a universal language understood by health professionals, researchers, policy makers, patients, and patient organizations.

Models to explain functioning

The organizational paradigm and Brofenbrenner's biopsychossocial theory applied to disability

Along the history different approaches to assess and intervene in disability were adopted. In fact, according Kuhn (1962) and Lakatus the whole scientific activity is regulated by rules and assumptions that constitute scientific paradigms. These paradigms change in the history and according to the scientific field, though there are points of contact (the scientific method, for example, is used in several sciences). According to Kuhn and Lakatus we can assume that the scientific process is not continuous but operated by revolutions. To determine the state of development of a discipline it becomes necessary to consider the paradigms that orientate it. Two major paradigms were used in the assessment and intervention of disability: the traditional paradigm and the organizational. The latter emerged in the '70s, but without the expected acceptance. Today, both paradigms continue to coexist. The traditional paradigm - often associated with the publication of the metric scale of Binet-Simon (Boake, 2002)- focuses on the diagnosis, on classifying in light of nosographic categories. Theoretical perspectives such as maturacionism or behaviorism fall in this paradigm.

Assessments allow the inclusion of a subject in a group with certain deficits or diseases. The diagnosis brings implicitly the idea of a prognosis, that should be understood as the natural evolution of the disease or disorder instead of the expectation of treatment. Considering for instance, disorders of the autism spectrum: when diagnosing such a disorder, a child is being placed in a group, assuming that he or she will develop a set of specific difficulties that are "pre-determined" or "pre-defined" at an early developmental stage. The diagnosis contains in itself the potential for development, and a binomial diagnosis-prognosis is established. Assessment has, following the traditional paradigm, a triple intentionality: to describe, to prognose and to trial according to the identified deficits.

Now-a-days, creativity and originality are emphasized and it is assumed that the individual should have the ability of learning and self-developing. The idea of the individual as agent of his own development is practically axiomatic today, but did not make any sense 60 years ago. One of the most important aspects of the organizational paradigm is the idea that prognoses are very fallible.

The organizational, ecodevelopmental or simply the new paradigm has essentially 3 specifying characteristics: it put the emphasis in the mutual dependence between the processes of evaluation and intervention, makes reference of the performances of the individual to a descriptive system of a developmental becoming and extends the focus of evaluation to the contextual determinants of the psychological development. The use of formal assessment instruments makes sense only in specific circumstances like the detection of cases at risk, cases of installed risk, the continuous gauging of the

adequateness of the intervention programs and in the development and gauging of the global success of the interventions.

The global objective of the evaluation according to the organizational paradigm is to document the processes underlying the observed performances of an individual with a triple finality: to determine the needs of the individual, to determine the eligibility of the individual relatively to the intervention and to plan the intervention. Besides disability, contextual determinants are also taken into account, considering that the environment can be adapted to the individual in a normalizing perspective.

The organizational perspective shares the gestaltic assumptions and those of the theory of the open system. The psychological development would be so a process of transformation of an irreducible system to the sum of the parts (Fischer & Bidell, 1998) Behaviour is seen as a global organization of the psychological activity that is structured in the framework of transactions between the individual and the environment (Sameroff & Mackenzie, 2003).

The solid articulations between the different domains of human functioning allow that the competences in a determined area support the competences in another domain, but also alert to the fact that a motor difficulty might have consequences at cognitive or affective level, for example. Different factors of different nature (biological, psychological, chemical, etc.) influence development, but do not operate in isolated or additive ways as defended by the etiological models, being instead inserted in a set of constellations of variables that are influenced in reciprocal way.

The organizational paradigm incorporates therefore the transactional perspective of Sameroff (Sameroff, 1986, 1992; Sameroff & Mackenzie, 2003),

the bioecological model of Bronfenbrenner (Bronfenbrenner, 1973; Bronfenbrenner & Ceci, 1994), Piaget's (Piaget, 1962; Piaget & Inhelder, 1947) and Vigotzky's conceptions between others, attracting attention for a multiplicity of factors that should be assessed in an integrated and holistic manner, the importance of the contexts of the individual with disability, the difficulty of producing predictions, but also the notion that there are different developmental pathways and that the option for each of them depends, in part, on the participation of the subject.

Brofenbrenner's ecological approach of the systems provides a framework for the study of human development taking into account the entire context of the individual, which includes a variety of systems. The environmental influence that can take on various levels, despite the interrelationships between these, is defined as microsystem, mesosystem, exosystem, macrosystem and cronosystem. A **Microsystem** consists of a set of activities, interpersonal relationships and roles played by the individual in the context in which they appears Examples of this are the relations between parents and children, relationships within the workplace, interactions in recreational institutions and others in which the individual participates . A **mesosystem** covers interactions between two or more contexts, for example the relations established between the family and community, the influence of the media or the health services and the family. **Exosystems** are all contexts, that influence the individual, but in which he or she is not directly involved in. Media, neighbors, social services are some examples of these types of context. A **Macrosystem** refers to the system of values and cultural beliefs of a society. In general all other subsystems are influenced by the macrosystem.

Bronfenbrenner did not study individual differences in great detail, focusing on individual functioning only when related to the relationship between the systems in which the person develops. Ecological systems and the relationships between intracontext and intercontext are the center of study. So one of the most relevant issues to the author consisted of intervention and how the variables interact and change the intracontext to produce the development of an individual (Bronfenbrenner, 1997).

International Classification of Impairment, Disabilities and Handicaps (ICIDH)

Clinicians have relied on classifications for the diagnosis of health conditions for almost the last 100 years (World Health Organization, 1996). However, the first classification addressing disability and the consequences of diseases was not published until 1980. This classification was called the International Classification of Impairment, Disabilities and Handicaps (ICIDH). The ICIDH, and the model supporting it, represented a real breakthrough in which the WHO recognized that the medical model and its associated International Classification of Diseases (ICD) (World Health Organization, 1996) did not address the consequences of chronic diseases. The ICIDH represented an international classification of disablement, suitable for research and a myriad of other uses, that appeared to embody the insights of the social model. The ICIDH has been used in dozens of contexts for a wide variety of purposes Đ health outcomes research, population surveys, codifying health information, vocational assessment and as an organizational basis for social policy (Bickenbach, et al., 1999).

However, in the ICDH disablement is modeled as a sequence of levels of health experience consequential upon some aspect of morbidity (disease, trauma, mental illness and chronic or age-related conditions). An initial pathological change, which need not be observable or experienced, may lead to awareness of `abnormalities of body structure and appearance and of organ or system function' (Bickenbach, et al., 1999). This is called an impairment, defined in the ICIDH as ``any loss or abnormality of psychological, physiological, or anatomical structure or function''. Impairments involve parts of bodies or body systems; they are temporary or permanent differences of structure or function.

More accurately, they are deviations from biomedical norms that are statistically grounded. They are observable and measurable. Should an impairment adversely affect the person's range of activities, how he or she actually acts or behaves, then the person will experience a limitation on the activities he or she can perform. This is a disability, defined as ``any restriction or lack (resulting from an impairment) of ability to perform an activity in the manner or within the range considered normal for a human being". Finally, impairments and disabilities may disadvantage the individual by limiting or preventing the fulfillment of six important `survival' roles: orientation, physical independence, mobility, occupation, social integration and economic self-sufficiency. When that happens, the negative social consequences, that is, the social disadvantages of being a person with impairments and disabilities, constitute a handicap, defined as a disadvantage for a given individual, resulting from an impairment or a disability, that limits or prevents the fulfillment of a role that is normal (depending on age, sex and social and cultural factors) for that individual".

At the levels of disability and handicap, the ICIDH recognizes the role of social environmental factors in the production of disablement. Impairments need not affect a person's activities; but even if they do, no disability will result if the activity is not something a person is expected to be able to do, or to do in one way rather than another. People with impairments and disabilities, moreover, will only be disadvantaged in a social, cultural or attitudinal environment in which having impairments and disabilities (or being perceived to) typically brings disadvantageous consequences. Despite the attempt to offer a nonmedical model of disablement, the promise was never fully, or clearly, realized (Bickenbach, et al., 1999). The root problem was a subtle ambiguity of

language that undermined the intended model. Try as the drafters might to insist that disabilities exist because of social expectations of normal performance and that handicaps are socially constructed disadvantages, they persisted in using language that suggest a very different picture:

"*Disadvantage accrues as a result of [the individual] being unable to conform to the norms of his universe. Handicap is thus a social phenomenon, representing the social and environmental consequences for the individual stemming from the presence of impairments and disabilities."* (World Health Organization, 1980, p. 29)

Although presumably not intended, this passage suggests that people are disadvantaged because of their disabilities alone, and that handicaps are caused by impairments and disabilities (Bickenbach, et al., 1999) . Though much is said in the commentary about the complexity of the relationships between the three levels, the diagram chosen to represent the overall model shows one-way arrows linking disease to impairment to disability to handicap. According to Bickenbach et al (1999) the user of the ICIDH cannot record, let alone measure, the effect that an unaccommodating environment has on people's lives. The user can record changes in a person's level of ability, but would have no way of knowing whether that was the result of changes to the person (rehabilitation), or changes to the social and physical environment (accommodation).

As far as the ICIDH is concerned, the social and physical world is immutable and benign. The underlying model does not clearly acknowledge that the

presence of social barriers and the absence of social facilitators play any sort of role in the creations of the disadvantages that a person with a disability experiences. This means that the ICIDH is vulnerable to the charge that it fails to provide a flexible tool for guiding research and data collection on all aspects of disablement (Bickenbach, et al., 1999). Impairments and their severity can be recorded, as can disabilities and their severity. But no more. The social model of disablement is only partly adopted and never operationalized. At best, it is a tool for research, administrative and planning uses by medical professionals and physical therapists who, for their purposes, focus entirely on the individual impairments and treat the environment as unchangeable. As it happens, though, several other functional assessment instruments are available for these purposes already (McDowell and Newell, 1996 quoted in Bickenbach, 1999). Maybe as a result of this, the ICIDH did not find worldwide acceptance (Gerold Stucki, 2005) been instead was criticized over time for the use of negative terminology, as well as for not explicitly recognizing the role of the environment in its model.

UPIAS/DPI

A year after the publication of the ICIDH, Disabled People's International (DPI) presented the UPIAS/DPI a classification that was based on a proposal presented in 1976 by a group of people with physical disabilities called the Union of the Physically Impaired against Segregation (UPIAS). This classification was a offered a two-element model which originally used the terms `disability' and `handicap', although later these terms were replaced by `impairment' and `disability' (see Driedger, 1989 and Barnes, 1991, p. 2±3, quoted in Bickenbach, 1999):

Impairment is the functional limitation within the individual caused by physical, mental or sensory impairment.

Disability is the loss or limitation of opportunities to take part in the normal life of *the community on an equal level with others due to physical and social barriers. (UPIAS, 1976, p. 3±4)*

Though the first definition is circular, taken together the definitions have the virtue of making explicit the effect of the social environment (Bickenbach, et al., 1999). According to UPIAS: "*it is society which disables physically impaired people. Disability is something imposed on top of our impairments by the way we are unnecessarily isolated and excluded form full participation in society. Disabled people are therefore an oppressed group in society*". (UPIAS, 1976, p. 3±4). Disability is, therefore, a loss or limitation of opportunity to participate brought about by social and physical barriers. Society disables people with impairments; disability is imposed on people. Impairment on the DPI/UPIAS model appears to refer to more or the less the same domain of functional limitations as found in the ICIDH (Bickenbach, et al., 1999). The nature of the

link between impairment and disablement is an important issue for any social theory of disablement, since without some researchable connection it would not be possible to distinguish the socially-created disadvantages of disablement from those of race, gender, class or economic status. If the UPIAS/DPI definition of `impairment' is troubling, it's definition of `disability' is even more problematic. Although the terms are by no means identical, disability in this model is parallel to handicap in the ICIDH, in the sense that both notions point to the disadvantages created by the social and physical environment (Bickenbach, et al., 1999).

Comparing the UPIAS/DPI to the ICIDH, in the latter it is perfectly possible for a person to have an impairment but experience no limitation in anything he or she can do. On the other hand, if a person wants to repair watches for a hobby, having what would in another person be a negligible hand tremor might make watch-repairing difficult or impossible (Bickenbach, et al., 1999). The ICIDH allows the establishment of relationships between "impairments" and "disabilities", which are inexpressible in the UPIAS/DPI due to the lack of a category for person-level activity (Bickenbach, et al., 1999). According to Bickenbach et al (1999) the authors of the UPIAS/DPI model have collapsed the notions of ICIDH-disability and ICIDH-handicap. This is a limitation of the model, because unless we can identify, classify and assess a person's performance given different environments, we have no way of showing whether, and how, any aspect of the environment constitutes a barrier. Nor do we have any basis for a therapeutic intervention to enhance that person's repertoire of abilities by means of surgery, physiotherapy, exercise, education or some other change to

the person. In the end, Bickenbach et al (1999) consider the UPIAS/DPI to be provocative but not operationalizable.

The International Classification of Functioning, Disability and Health (ICF)

The International Classification of Functioning, Disability and Health (ICF) (World Health Organization, 2001), the successor classification of the ICIDH, addresses all previous criticisms by incorporating environmental and personal factors and by using more neutral concepts. The ICF and the model that forms the basis for the classification (Figure 1) were approved and unanimously endorsed by all member states at the 54th World Health Assembly in May 2001. Since its endorsement they have provided a new foundation for our understanding of health, functioning, and disability. They represent a universal model and a classification system to comprehensively describe human experience in relation to functioning and disability (G. Stucki, et al., 2007).

The ICF and its model achieve a synthesis and provide a coherent view of the main, different perspectives of functioning and disability from the biological, individual, and social perspectives. Thus, based on the ICF, the management of functioning and disability requires a comprehensive approach that not only targets aspects intrinsic to the person but also aspects of the environment, and requires actions be taken across sectors that include health, labor, education and social-affairs.

Figure 1 depicts this integrative perspective of functioning and disability of ICF.

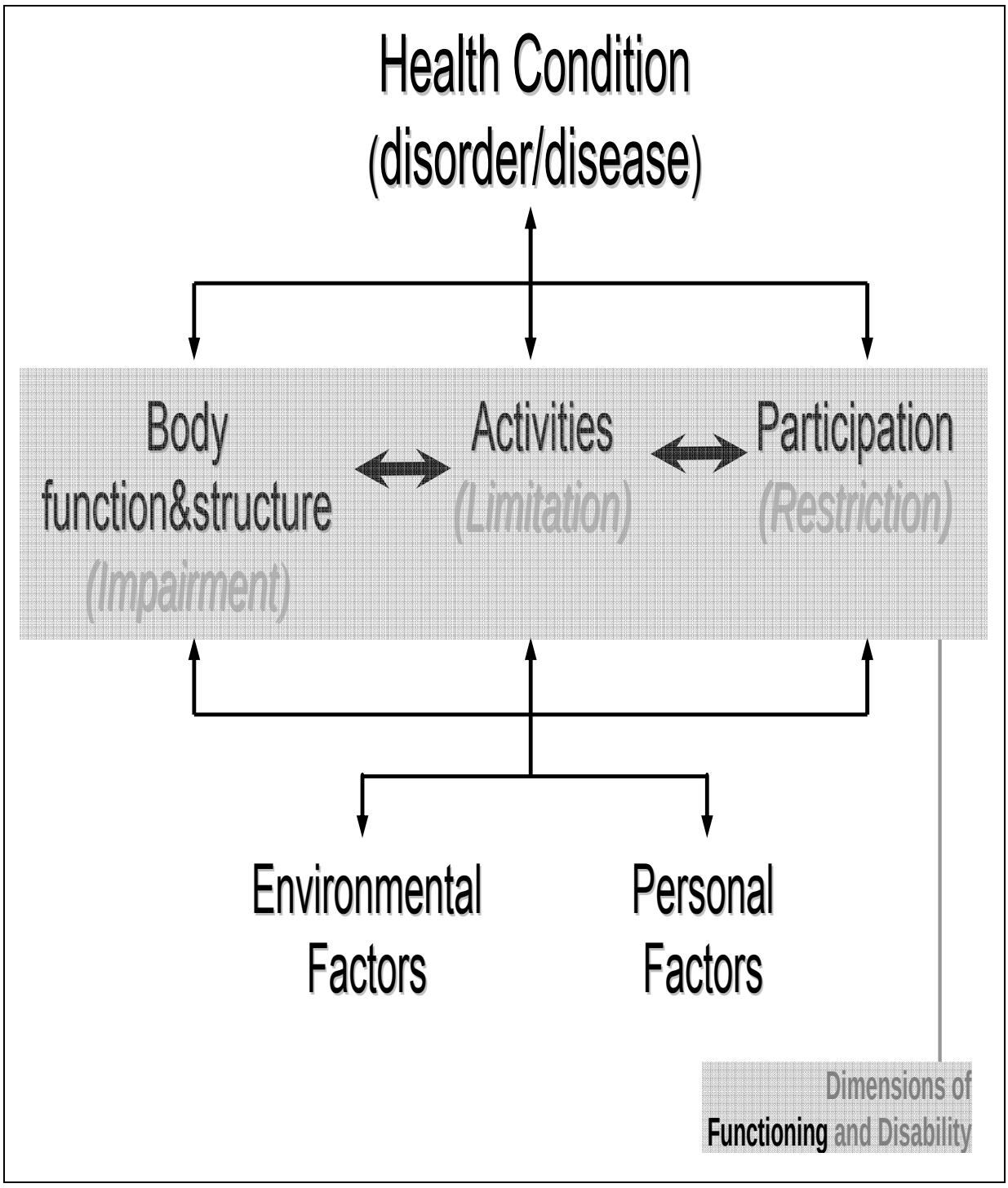


Figure 1: The model of functioning and disability on which the ICF is based

The model identifies three components of the dimension **functioning**, namely **body functions and structures**, **activities,** and **participation**. Problems or difficulties in these components are called **impairments, activity limitations,** and **participation restrictions**, that is, components of the dimension of **disability.** Functioning and disability are both affected by interactions between health conditions and **contextual factors** (**environmental and personal**) (see Figure 1). This means that, to describe a person's functioning, the level of functioning as pertains to body functions and structures, activities, and participation must be reported. To describe a person's disability, the level of impairment in body functions and structures, the level of limitation in activities and of restriction in participation must be reported. Moreover, to understand the experience of functioning and disability of a person with one or more health conditions, knowledge of the health conditions and relevant influencing factors in the environment and of the person is also a prerequisite.

Since the approval of the ICF, there has been a wide range of implementation activities worldwide. They include the use of the ICF as a basis for disability surveys, in the education of health professionals, in case management and as a new paradigm of research. International organizations such as the Outcome Measures in Rheumatoid Arthritis Clinical Trials [OMERACT] have decided to use the ICF as their reference framework for the development of measures and standards (Gerold Stucki, Boonen, Tugwell, Cieza, & Boers, 2007). Also, an increasing number of research papers are using the ICF as a starting point when examining aspects of functioning or when planning and reporting studies (Jerosch-Herold, Leite, & Song, 2006). There are over 600 ICF publications

since its approval in 2001, reflecting the interest, relevance, and impact of its application in health research worldwide.

With the recent approval of the International Classification of Functioning, Disability, and Health (ICF) (World Health Organization, 2001) by the World Health Assembly there is now an universally accepted framework to classify and describe functioning, disability and health.

The ICF is one of the World Health Organization's (WHO) family of international classifications, of which the best known member in clinical medicine is the International Statistical Classification of Diseases and Related Health Problems (ICD-10) (World Health Organization, 1996). Within this context of the WHO international classifications, the ICF complements the information on diagnoses, diseases, disorders and other health conditions provided by the ICD-10 by classifying information on functioning and disability. Thus, ICD and ICF are complementary classifications from which WHO envision a common application in clinical medicine and research.

The ICF contains an exhaustive list of globally acceptable descriptions of "what" can be relevant to describe functioning, disability and health when persons have health conditions. In other terms, the ICF contains the "words" of an international vocabulary to describe functioning, disability and health. Thus, the ICF is usually referred to as the unified and standard language of human functioning, disability and health.

The "words" of the vocabulary contained in the ICF are called ICF categories. The ICF contains a total of 1454 ICF categories included in one of the different components of the model of functioning, disability and health on which it is based (Figure 1): 493 body functions, 310 body structures, 393 activities and

participation domains, and 258 environmental factors. The personal factors component has not yet been classified.

Similar to a textbook or manual, the ICF categories are hierarchically organized. The first level of this hierarchy and the first frame of reference on the basis of which we can find information within the ICF is made up of chapters (categories at the first level). Each chapter consists of second-level categories and, in turn, these are then comprised of third- and fourth-level categories. The 2nd- 3rd- and 4th-level categories correspond to subheadings in textbooks or manuals and they represent a more detailed frame of reference to find information within the ICF. Figure 2 illustrates the structure of the ICF. An example from the body functions component is presented in the following:

'b1 Mental functions' (first chapter level)

'b114 Orientation functions' (second level)

'b1142 Orientation to person' (third level)

'b11420 Orientation to self' (fourth level).

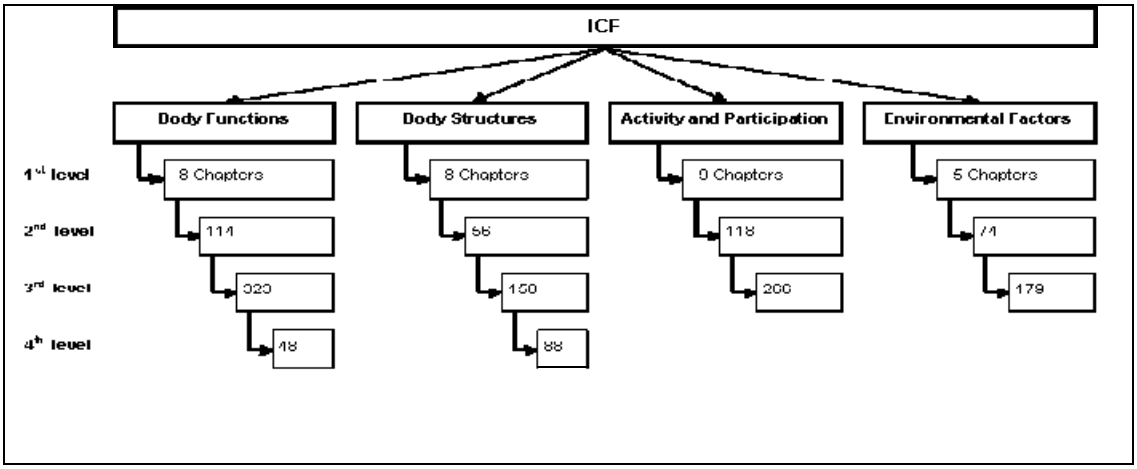


Figure 2: The structure of the ICF and the distribution of the ICF's 1454 categories across its four components and four levels of hierarchy

The ICF also comprises the so-called qualifiers, which quantify the severity of the impairment, limitation or restriction in the different ICF categories. The ICF qualifier is simply a rating scale with five response options: 0 = no impairment, limitation or restriction, 1 = mild, 2 = moderate, 3 = severe, and 4 = complete impairment, limitation or restriction. The qualifier for the environmental factors has nine response options ranging from +4 (complete facilitator) to -4 (complete barrier), with a zero value indicating neither a facilitator nor a barrier.

Since the ICF categories are usually accompanied of a qualifier rating, they can be confounded with items used, e.g., in patient-reported outcomes. However, the ICF categories are different from items in the sense that ICF categories are agreed-on descriptions of "what" can be relevant to people with a health condition experiencing decrements in functioning. There is a wide range of items potentially suitable for the measurement of a specific ICF category or a set of ICF categories. For example, there is a large number of items suitable to operationalize the ICF category b130 Energy and drive functions, for example, "I feel very active" from the Multidimensional Fatigue Inventory, "I felt that everything I did was an effort" from the Center for Epidemiological Studies Depression Scale and "Did you feel tired?" from the Short Form-36.

One could say that while there is a finite number of ICF categories necessary to describe functioning, disability and health, there is, at least in principle, an infinite number of items potentially useful to measure those categories. Similarly, the ICF categories, such as b420 "Blood pressure" or b4110 "Heart rate" should not be confused with clinical tests. The ICF categories are needed when specifying "what to measure" while items and clinical tests including

imaging, laboratory tests or capacity tests are needed when specifying "how to measure".

In summary, the ICF categories contained in the ICF represent the whole universe of meaningful units necessary to describe the experience of people in relation to functioning, disability and health.

On the other hand, practical tools are necessary to make the ICF useful in clinical practice.

Instruments based on the ICF

The ICF Checklist

The ICF checklist (World Health Organization, 2001b) is composed by the most relevant ICF categories and was developed to facilitate the application of ICF in clinical settings and in research projects by qualifying the individuals' functioning profile in a simple and time efficient manner (World Health Organization, 2001b; Ewert et al., 2004). It represents a selection of 128 the ICF categories at the first and second levels of the ICF hierarchy from the entire the ICF classification system. It is a 12-page instrument, which is filled out by a health professional and not by the patient.

For the completion of the ICF checklist, multiple data sources (such as self report, medical examinations, clinical records, report from family members etc.) to make a clinical judgment can be used. Coding rules have been published by the Disability Italian Network's (Leonardi et al., 2005).The ICF checklist covers all the ICF components: 32 codes (25%) of *Body functions*, 16 (13%) of *Body structures*, 48 (37%) of *Activities and Participation*, and 32 (25%) of *Environmental factors*.

The Body Structures chapter contains:

- eleven codes from the chapter 1 "Mental functions",
- four codes from chapter 2 "Sensory functions and Pain",
- one code from chapter 3 "Voice and Speech functions",
- five codes from chapter 4 "Functions of the Cardiovascular, Haematological, Immunological and Respiratory Systems"",
- four codes from chapter 5 "Functions of the Digestive, Metabolic and Endocrine Systems",

- two codes from chapter 6 "Genitourinary and Reproductive functions",

- four codes from chapter 7 "Neuromusculoskeletal and Movement Related functions" and

- one code, at the first level of the classification, referring to chapter 8 "Skin and related structures".

The "Body Functions" domain should be assessed by a health professional using the appropriate qualifier of "extent of impairments", from 0 (no impairment) to 4 (complete impairment). According to the definition, an impairment in a body function, refers to "problems in a body function as significant deviation or loss". Additionally, qualifier 8 "not specified" can be used in case there is insufficient information to specify the severity of the impairment and 9 in case the code is not applicable (e.g., menstrual functions in post-menopausal women).

The *Body Function* codes are divided into 8 chapters:

- 1 "Structures of the Nervous System "(2 codes);

- 2 "The Eye, Ear and related structures" (1 code),

- 3 "Structures involved in Voice and Speech" (1 code),

- 4 "Structure of the Cardiovascular, Immunological and Respiratory Systems" (2 codes),

- 5 "Structures related to the Digestive, Metabolism and Endocrine Systems" (1 code),

- 6 "Structure related to Genitourinary and Reproductive System" (2 codes),

- 7 "Structures related to Movement" (6 codes),

- 8 "Skin and related Structures" (1 code).

Health professionals should use two qualifiers to address this domain. The fist one referrers to extent of impairment and is identical to the one in use for the Body Functions domain. The second one refers to the nature of the change and should be applied as follows: "0 No change in structure";

"1 Total absence" "2 Partial absence"; "3 Additional part" "4 Aberrant dimensions" "5 Discontinuity"; "6 Deviating position"; "7 Qualitative changes in structure, including accumulation of fluid"; "8 Not specified" and "9 Not applicable".

The *Activities & Participation* codes are divided into 9 chapters:

- Learning and applying knowledge (6 codes);
- General tasks and demands (2 codes);
- Communication (5 codes);
- Mobility (6 codes);
- Self-care (7 codes);
- Domestic life (4 codes);
- Interpersonal interactions and relationships (7 codes);
- Major life areas (6 codes); and
- Community, social and civic life (5 codes).

Activities and Participation codes are qualified by two different measures: *capacity* and *performance*. *Capacity* is a qualifier that exposes the ability of an individual to do a task or an action by her/himself, the highest probable level of functioning that a person may reach - without considering environmental information. *Performance* describes the extent to which an individual can do an activity in his or her current environment - this context includes the environmental factors, all aspects of the physical, social and attitudinal world.

Activities and Participation codes can be qualified by using a 5-point Likert scale: from 0 ('no impairment') to 4 ('complete 10 impairment'). In addition, there are two more possible values: 8 'not specified' and 9 'not applicable'.

The Environmental Factors codes are divided into 5 chapters:

- chapter 1 "Products and Technology" (6 codes),
- chapter 2 "Natural Environment and Human made changes to the Environment" (3 codes),
- chapter 3 "Support and Relationships" (7 codes),
- chapter 4 "Attitudes" (7 codes) and
- chapter 5 "Services, Systems and Policies" (9 codes).

Here the health professional has to decide whether the environmental factor constitutes a facilitator or a barrier to the participation of the individual and qualify them using a 9 point Likert scale: from -4 (complete barriers) to 4 (complete facilitator). Positive and negative values indicate facilitators and barriers, respectively.

WHODAS-II

The World Health Organization Disability Assessment Schedule 2.0 (WHODAS-2) REF is a disability assessment instrument based on the conceptual framework of the ICF that was created in 1998 by the WHO. It provides a global measure of disability and 7 domain-specific scores. It contains 36 items on functioning and disability with a recall period of 30 days covering 7 domains: *Understanding and Communicating (6 items), Getting around (5 items)*, *Self-care (4 items)*, *Getting along with others (5 items)*, *Life activities: household (4 items), Life activities: work/ school (4 items)*, and *Participation in society (8*

items). Response options go from 1 (no difficulty) to 5 (extreme difficulty or can not do). WHODAS-2 scores are computed for each domain by adding the item responses (the score computation allows for up to 30% of missing items per domain) and transforming them into a range from 0 to 100, with higher scores indicating higher levels of disability. A global score is also calculated from all the 36 items or from all except the Life activities ones -work/school- when people don't not apply for this domain items.

According to Garin et al, WHODAS-2 has shown good metric properties among patients with chronic conditions in Europe: a very high reliability, good ability to discriminate among known groups and adequate capacity to detect change over time. According to their validation study the WHODAS-2 is able to detect differences between clinical-severity groups (Garin et al.). Those patients classified as severe reported worse disability scores than mild patients, with a large difference for most of the health conditions (66%), and a moderate difference for 25% of them. The utilization of the WHODAS-2 as a common, international, and interdisciplinary instrument to measure disability is recommended. Furthermore, it is of special relevance because it is the only measure based on the ICF biopsychosocial model.

ICF Core Sets for Specific Chronic Conditions

ICF's framework is based on a comprehensive and integrative perspective covering functioning and disability with its components Body Structures and Functions and Activity and Participation as well as Personal and Environmental Factors.

A classification needs to be exhaustive by its very nature. In relation to the ICF, exhaustiveness refers to the coverage of the complete spectrum of health and health-related domains that make up the human experience of functioning and disability, and the complete spectrum of environmental factors that influence that experience of functioning and disability. The ICF appears to fulfill the formal criteria of exhaustiveness when considering both the patient and the health professional perspective, especially in relation of the bandwidth of covered domains. However, exhaustiveness is often related to complexity and, most importantly, to impracticability. The criticism is often heard that the ICF is too comprehensive and too complicated for use in clinical practice. Since its classification with more than 1400 categories can serve as a reference but is not applicable in clinical practice, tools such as ICF Core Sets (G Stucki, Cieza, et al., 2002) are needed to make the ICF useful for medicine (G Stucki, Ewert, & Cieza, 2002). Each ICF Core Set represents a number of ICF categories as part of the entire classification, selected based on a scientifically structured process. The joint use of the ICF and the International Classification of Diseases (ICD-10) needs to be addressed when applying the ICF to medical practice. Therefore, the main goals of the development of ICF Core Set for chronic conditions are to make the ICF practical for research and clinical practice and to link the ICF to the ICD. In line with the concept of condition-specific health-

status measures, specific conditions or diseases are linked to salient ICF categories of functioning.

To date, ICF Core Sets have been developed for 12 chronic health conditions (A Cieza et al., 2004; G Stucki & Grimby, 2004; Ustun, et al., 2004). ICF Core Sets for other chronic conditions including psoriasis, psoriatic arthritis, ankylosing spondylitis, systemic lupus erythematosus, scleroderma, spinal cord injury, tumours of the upper digestive tract and visual impairment are currently being developed by the ICF Research Branch in Munich in collaboration with partner organizations worldwide. For people after an acute episode, ICF Core Sets need to be useful in the context of the acute hospital and the context of early post-acute rehabilitation. To address the organ-system rather than the condition specific approach, which reflects the care reality in most countries and seems most practical, seven ICF Core Sets have also been developed for the acute hospital and early post-acute rehabilitation facilities (A Cieza, et al., 2004; Ewert, et al., 2004; Grill, Ewert, Chatterji, Kostanjsek, & Stucki, 2005b; G Stucki, Cieza, et al., 2002; Gerold Stucki, et al., 2005a) and for the acute hospital and early post-acute rehabilitation setting (Grill, Ewert, Chatterji, Kostanjsek, & Stucki, 2005a; Gerold Stucki, Stier-Jarmer, Grill, & Melvin, 2005b; G Stucki, Ustun, & Melvin, 2005).

For each health condition, both a Brief ICF Core Set and a Comprehensive ICF Core Set have been established.

The Brief ICF Core Set is intended to be rated in all patients included in a clinical or epidemiologic study, and the Comprehensive ICF Core Set is intended to guide multidisciplinary assessments in patients with a specific condition. A Brief ICF Core Set for a specific condition includes as few

categories as possible to be practical, but as many as necessary to be sufficiently comprehensive to describe the typical spectrum of problems in functioning of patients with a specific condition in clinical studies and possibly clinical encounters.

The intention is for the categories of the Brief ICF Core Set for a specific condition to serve as a minimum data set that will be reported in every clinical study to provide a standardized description of the burden of disease. Therefore, the list needs to be as short as possible.

The Comprehensive ICF Core Set for a specific condition is a list of ICF categories that includes as few categories as possible to be practical, but as many as necessary to be sufficiently comprehensive to describe the typical spectrum of problems in functioning of patients with a specific condition in a comprehensive, multidisciplinary assessment. Obviously, this list will be considerably longer than the Brief ICF Core Set.

Table 1 shows the number of ICF categories per ICF component included in the 12 Brief and Comprehensive ICF Core Sets for chronic conditions that have been so far developed.

Table 1: ICF Core Sets for chronic conditions. Figures in the columns refer to Brief ICF Core Sets while the figures in the parentheses refer to the comprehensive ICF Core Set.

Number of categories	Total	BF	BS	A & P	EF
CWP	24 (67)	9 (23)	0 (1)	10 (27)	5 (16)
LBP	35 (78)	10 (19)	3 (5)	12 (29)	10 (25)
OA	13 (55)	3 (13)	3 (6)	3 (19)	4 (17)
OP	22 (69)	5 (15)	4 (7)	6 (21)	7 (26)
RA	39 (96)	8 (25)	7 (18)	14 (32)	10(21)
CIHD	36 (61)	10 (14)	1(1)	13 (17)	12 (29)
DM	33 (99)	12 (36)	6 (16)	5 (18)	10 (29)
Ob	9 (109)	3 (30)	0 (18)	4 (28)	2 (33)
OPD	17 (71)	5 (19)	3 (5)	5 (24)	4 (23)
BC	40 (80)	11 (26)	5 (9)	11 (22)	13 (23)
D	31 (121)	9 (45)	0 (0)	12 (48)	10 (28)
ST	18 (130)	6 (41)	2 (5)	7 (51)	3 (33)

BF: Body Functions, BS: Body Structures, A & P= Activities and Participation, EF: Environmental Factors.

CWP: Chronic Widespread Pain, LBP: Low Back Pain, OA: Osteoarthritis, OP: Osteoporosis, RA: Rheumatoid Arthritis, CIHD: Chronic Ischemic Heart Diseases, DM: Diabetes Mellitus, Ob: Obesity, OPD: Obstructive Pulmonary Diseases, BC: Breast Cancer, D: Depression, ST: Stroke.

The development of the Brief and Comprehensive ICF Core Sets for Chronic conditions involved a formal decision-making and consensus process integrating evidence gathered from preliminary studies and expert opinion. For each health condition, the preliminary studies included a Delphi exercise (Weigl et al., 2004), which represents the expert view, a systematic review (Thomas Brockow, Alarcos Cieza, et al., 2004; Thomas Brockow, Katharina Duddeck, et al., 2004) on outcomes used in randomised clinical trials, which represents the view of researchers performing studies, and an empiric data collection, using

the ICF checklist representing the perspective of patients undergoing inpatient or outpatient rehabilitation (Ewert, et al., 2004). Relevant ICF categories were identified based on these preliminary studies. The lists of these identified categories represented the starting point of the decision-making and consensus process at the conferences with experts from all over the world.

To ensure expertise and broad representation within the context of a feasible and affordable decision-making process, (1) formal cooperations with appropriate organizations were established, (2) clinicians involved in the preliminary studies were invited, (3) international and regional societies (or working groups) were identified and their members contacted, (4) opinion leaders in the different health conditions were identified and invited, and (5) experts in the fields of functioning and health, quality of life, health statistics, and public health from developing countries were contacted by the WHO and invited to the conference.

During the conferences, the first meeting consisted of a half-day training workshop, in which all participants were familiarized with the ICF framework and classification and informed of the results from the preliminary studies. Participants were provided with summary sheets containing both the identified ICF categories and the results of the preliminary studies.

The ICF categories to be included in the ICF Core Sets were then identified in an iterative decision-making process with discussions and voting. In the process, ICF categories which were either clearly relevant or irrelevant according to preset decision rules were excluded from further discussion. Attention could then be focused on the remaining controversial categories.

Immediate feedback was provided on the voting results during the whole decision-making and consensus process.

The decision-making process consisted of two major parts. In the first part, the participants were requested to select the Comprehensive ICF Core Set according to the above definition. In the second part, the participants were requested to select the Brief ICF Core Set. This second part exclusively involved the categories of the Comprehensive ICF Core Set.

The Brief ICF Core Sets and the Comprehensive ICF Core Sets that were developed so far are preliminary and are now being tested and validated with a number of methodological approaches, including empirical studies, focus groups with patients and Delphi exercises with different professional groups.

The main goals of the testing and validation process are 1) to verify whether the ICF categories included in the comprehensive ICF Core Sets really represent relevant problems encountered in people with the condition under consideration throughout the world, 2) to identify whether there are relevant categories currently missing in the comprehensive ICF Core Sets and 3) to examine the relevance of the categories included in the Brief ICF Core Set and to provide information for the decision regarding the cut-off for inclusion in the Brief ICF Core Sets.

More than 45 countries and 250 study centres are currently participating in the empirical studies. Some countries, including Brazil, Germany, Greece, Italy and Switzerland, have established networks and have sought funding for the testing and validation. In cooperation with the European League against Rheumatism (EULAR) and partner institutions in Vienna, Maastricht and Oslo, the five

musculoskeletal ICF Core Sets are currently being tested in 20 European countries.

The protocol for the empirical worldwide testing is based on a standardized protocol developed at the ICF research branch of the WHO FIC CC (DIMDI) in Munich in collaboration with the CAS team at WHO.

As a conclusion, the ICF Core Sets simply represent lists of ICF categories telling possible users "what" has to be considered or assessed in patients with determined health conditions. The ICF Core Sets do not go into the question of 'how to measure' each of the ICF categories of which they are comprised. Even whether to apply them in combination with the ICF qualifier remains open to the possible user.

The ICF Core Sets can be used for many different purposes. They can be used as condition-specific international standards to describe functioning and disability in a clinical encounter or in a clinical study to develop measures that enable the assessment of functioning and disability to develop patient-reported instruments as in the WHO Disability Assessment Schedule II (Posl, Cieza, & Stucki, 2007),to plan and report investigations as shown in Cieza & Stucki 2005 (Alarcos Cieza & Stucki, 2005), to study the content validity of patient-reported instruments as shown in, for example, Cieza & Stucki 2005, and to instruct clinicians and health professionals in training as shown in, for example, Cieza & Stucki 2007 (Cieza A, 2007).

Objectives

The objective of the project was the development of an internationally accepted, evidence-based, reliable, and valid Comprehensive ICF Core Set for BD and a Brief ICF Core Set for BD. Since functioning is an important outcome for individuals with BD, it would seem most helpful to link this condition to salient ICF categories of functioning. This project was a cooperative effort of the department of Psychiatry at Autónoma University (UAM) in Madrid, the Bipolar Disorders Programme at the Hospital Clinic in Barcelona and the CF Research Branch of the WHO Collaboration Centre of the Family of International Classifications at the Ludwig-Maximilian University in Munich, Germany.

Even though there are some singularities in the process ICF Core Sets for Bipolar Disorders were developed, and as explained in the previous section, the ICF Core Sets development always follows two principles. First, the process is an evidence-based process that integrates the information collected in preparatory studies representing three different views in medicine: the view of clinicians and health professionals, the view of patients, and the view of clinical researchers. Second, the process is a consensus-building process involving clinicians and other health professionals from the six WHO world regions (the Eastern-Mediterranean, the South-East-Asian, the Western-Pacific, and the European regions, and the region of the Americas). This second principle is of special importance from the WHO and international perspectives.

ICF Core Sets always include as few ICF categories as possible to be practical, but as many as necessary to be sufficiently comprehensive to describe the

typical spectrum of problems in the functioning of patients with health conditions.

It is noteworthy that the ICF Core Sets for BD are not intended to substitute current instruments to assess health status and quality of life in the area of BD. ICF Core Sets for BD are meant to provide an internationally agreed on framework of what should be assessed irrespective of how this is assessed. Thus, the ICF Core Sets for BD could also serve as a reference to compare the content of currently used instruments and the results of studies using different instruments. Moreover, new ICF based instruments might be developed to provide a precise assessment of the relevant patients' functional problems included in the ICF Core Sets for BD.

The present project includes three studies, addressing a) the perspective of the researcher; b) the perspective of the individual with bipolar disorder and c) the perspective of the experts in the bipolar disorder field.

The perspective of the researcher facilitated a deeper understanding on the current status of the art regarding BD research. A number of studies have addressed the levels of functioning and disability of persons with BD (Huxley & Baldessarini, 2007; J. Jaeger & Vieta, 2007; Martinez-Aran et al., 2007; Mur, Portella, Martinez-Aran, Pifarre, & Vieta, 2009). However, while there is some standardization regarding diagnostic measures, a large variety of instruments have been used to assess functioning and disability in this population (Rosa et al., 2007; Vieta et al., 2007). This is, in part, because there is no set of domains that defines "what should be measured" to comprehensively describe the burden of BD. An in-depth understanding of the outcome domains that have

been addressed in studies of BD in recent years can help to advance the field in this respect.

In addition, the knowledge about the outcome variables used in the BD literature also shed light on whether we are disregarding relevant outcomes important to persons with BD, such as aspects related to participation. The knowledge about what have been studied so far can direct future interventions and the selection outcomes variables. Based on the ICF, it is now possible to identify which areas of functioning and disability have been most frequently used to describe burden of BD and to compare the concepts contained in different outcome studies (A. Cieza et al., 2002a).

On the other hand, for identifying concepts of functioning and health relevant to people with Bipolar Disorder (BD) it is important to include the perspective of those who experience the health problem because personal values for outcomes vary between and within individuals and professionals. Qualitative methodology provides the possibility to explore the perspective of those who experience the health problem, i.e. the so-called patient perspective. Moreover, qualitative methodology can allow the identification of patterns and configurations among variables and to make distinctions (Sofaer, 1999).

One possible approach to identify the prototypical spectrum of functioning and health of individuals affected with BD is to individually interview patients. Evidence shows that in an appropriate atmosphere it is possible to collect subjective data on how the patient experiences his condition. The main goal of this study is to identify relevant aspects and problems of BD disorder according to the patient's own perspective and within the ICF framework.

Patients experience diseases and their consequences. They are the experts regarding impairments, activity limitations, and participation restrictions associated with health conditions (Weston, 2001). They are also the ones who are exposed to supportive and/or incapacitating environments and who experience the consequences thereof. Thus, information related to the experiences of patients ranks among the most valuable types of information when studying the content validity of the ICF.

Qualitative methods are the most appropriate methods to study the experiences of patients, or what is most frequently called the 'patient perspective' (Carr et al., 2003). Qualitative methods are now widely used and increasingly accepted in health research and health-related sciences (Giacomini & Cook, 2000; Weston, 2001) . Unlike quantitative methods, qualitative methods ask open-end questions, to which the individuals concerned can respond in their own words, using their own categorizations and perceived associations. Since the researcher raises questions, the data collection maintains a certain structure (Pope, Ziebland, & Mays, 2000).

Finally, the perspective of international experts with different professional background allowed us to include factors that are important for individuals leaving in different cultures and that are commonly addressed by different health professional conducting evaluations and interventions in their own field and therefore contribute to make the ICF useful in clinical practice and for multidisciplinary teams. This perspective was addressed by conducting a survey online.

The question which ICF categories are to be included in the ICF Core Sets for BD was answered on the basis of the information gathered during the

preparatory phase of the project. The most plausible and adequate method to answer that question seems to be agreement among experts. Hence, an ICF Core Set Consensus Conference was organized. The information collected during the preparatory phase was presented and experts in the field of BD worked actively together to deal with the complex problem of selecting the ICF categories. The methods selected to regulate the group dynamic and the teamwork during the conferences are the "Nominal-Group Technique" (Delbecq, Van de Ven, & Gustofon, 1975).

Specific Objectives

The ICF Core Sets for BP were defined at a ICF Core Set Consensus Conference which integrated evidence from different preparatory studies: a) a systematic review regarding the measures used in clinical trials and selected observational studies, b) a qualitative study using individual interviews with patients with BD c) an expert survey with health professionals from different health professions worldwide and d) an empirical, cross-sectional study. Each of these studies was conducted with a specific objective:

a) Systematic Literature Review

The objective of this systematic review was to study what the relevant outcomes in the field of BD are by means of identifying and quantifying the concepts addressed in the outcome variables in interventional and observation studies, using the ICF as a conceptual framework. The results of this review will be one of four sources of information that will contribute to the development of ICF Core Sets for BD. The specific aims of this review were: 1) to determine the

frequency of ICF categories linked to the concepts contained within the outcome variables used in published studies, 2) to explore differences regarding the areas of functioning and disability studies across different study types, and 3) to examine which standardized diagnostic instruments as well as consumer-oriented outcomes have been applied in individuals with BD and how often.

b) Qualitative study

The main goal of this study is to identify relevant aspects and problems of BD disorder according to the patient's own perspective and within the ICF framework. The main objectives are 1) to explore and understand the perspective of patients with BD on functioning and health using a qualitative approach and 2) to identify concepts of functioning and health important to these patients. The specific goals are 1) to gather information on body functions affected in patients suffering from BD according to their own point of view; 2) to identify body structures that are referred by patients as being impaired due to BD; 3) to describe what personal factors influence the way patients cope with their disorder in a positive or negative way and 4) to investigate what environmental factors play a significant role on living with BD.

c) Expert survey

The objective of the expert survey is to explore the expert perspective on relevant problems of individuals with Bipolar Disorders (BD). The specific aims are (1) to identify problems in functioning important to patients with BD and (2) to quantify these problems using the ICF.

d) ICF International Core Sets Consensus Conference for BD

The objective of the ICF Core Set Consensus Conference was to arrive at an international consensus on the most adequate ICF categories to be included in the ICF Core Sets for BD.

Hypotheses

While designing the present project, the methodology was chosen to address the following hypotheses:

1) The ICF is a content valid classification to address the problems of persons with bipolar disorders from their own perspective.

2) The ICF Core Sets for BD will share categories with the previously published ICF Core Sets for Depression.

3) The ICF domain that will be mostly represented in the ICF Core Sets for BD will be Activities and Participation.

4) The Body Structure s110-"Structure of the brain" or a more specific category within the brain structure will be the only Body Structure in the ICF Core Sets for BD.

5) The Activities and Participation ICF domain will be higher represented when addressing the Individual Perspective than in the other studies.

Methodology

The ICF Core Sets for BD were defined at a ICF Core Set Consensus Conference which integrated evidence from a) a systematic review regarding the measures used in clinical trials and selected observational studies, b) a qualitative study using individual interviews with people with BD, c) an expert survey with involvement of health professionals of different professions and d) an empirical study. A summary of the methods of these so called preparatory studies and the ICF Core Set Consensus Conference is shown in Table 2.

Figure 3 shows a summary of the time schedule for the development of the ICF Core Sets for BD.

With this study design all relevant perspectives were addressed adequately. The researcher perspective was addressed with the systematic review. The patient perspective was addressed in a qualitative study using individual interviews. Finally, the experts' opinion involving health professionals from the different backgrounds and specifications was addressed with the expert survey.

Table 2: Summary of the methods of the preparatory studies and the ICF Core Set Consensus Conference

Preparatory Studies	**Methods**	**Objectives**	**Specifics of ICF Core Set development for** BD
Qualitative study	Individual interviews are a qualitative method involving patients as experts of their health condition and functioning.	(1) to identify the most relevant problems of individuals with BD from the patient perspective (2) to quantify the problems using the ICF as a reference	According to the patient perspective a qualitative study using individual interviews is conducted with people with BD. A topic guide containing five open-ended questions regarding the components of the ICF will be used.
Expert survey	The expert survey is an electronic-based survey involving different health professionals worldwide.	(1) to identify the most relevant problems of individuals with BD from the expert perspective (2) to quantify the problems using the ICF as a reference	According to the need of the worldwide perspective, the aim is to include experts from all over the world, from different health professions and physicians with different specializations.
ICF Core Set Consensus Conference	The "Nominal-Group Technique" is a consensus planning tool that helps prioritise issues during the conference.	To develop *ICF Core Sets* in a formal decision-making and consensus process, integrating evidence gathered from preparatory studies.	The number of groups is set at 3 including at least 7 experts to address the large interest and to be able to involve the different professions and regions of the world. Each group consists of different health professionals who should work together in the spirit of the multi-professional and multi-disciplinary approach.

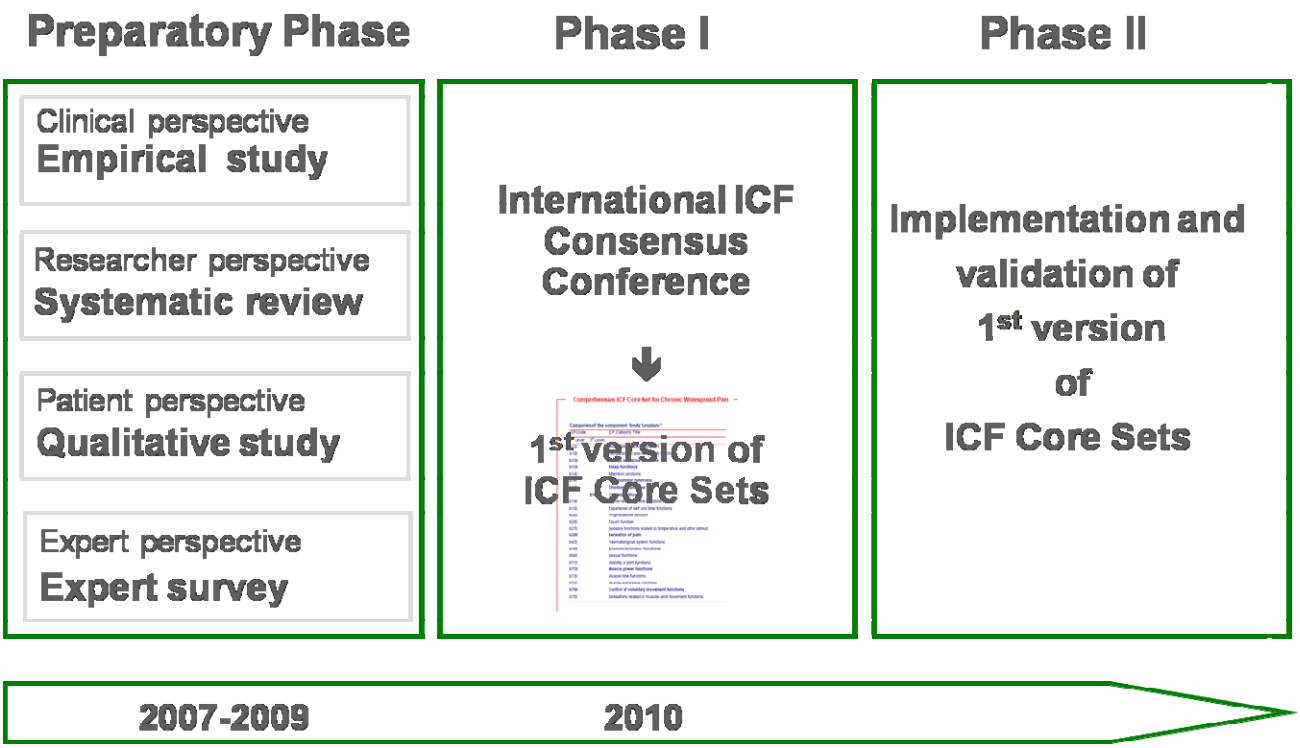


Figure 3: Time schedule and phases of the project

Specific Methods

a) Systematic Literature Review

Study Design

A systematic review was performed with the following three steps: step 1, selection of studies; step 2, extraction of outcome variables; and step 3, linkage of the concepts contained within the outcome variables to the corresponding categories of the ICF. All steps were conducted by two independent reviewers and followed a methodology that has been developed and implemented for the same purposes by the ICF Research Branch at the Ludwig-Maximilans University in Munich, Germany, in collaboration with the World Health Organization for different health conditions (Thomas Brockow, Alarcos Cieza, et al., 2004; Geyh, Cieza, Kollerits, Grimby, & Stucki, 2007; Tschiesner, Rogers, Harreus, Berghaus, & Cieza, 2009; Weigl, Cieza, Cantista, Reinhardt, & Stucki, 2008)

In Step 1, *selection of studies*, publications were located in MEDLINE® (via Pubmed) and PsycINFO using the search terms "bipolar disorder*", "bipolar patient*", "bipolar depression", "mania" and "function*". All searches were automatically limited to English-language articles published between 2000 and 2006, referring to studies conducted with human participants. The abstracts of the retrieved articles were checked, applying eligibility criteria. For the selected articles, the original study reports were ordered and reviewed, again applying the same eligibility criteria.

In Step 2, *extraction of outcome variables*, all types of outcome variables and specified characteristics of the study were extracted, including the type of

intervention (pharmacological, non-pharmacological and combined), the type of BD, and the polarity at the time of the study (depressive, manic, mixed and euthymic).

Outcome variables included clinical parameters, as well as diagnostic and standardized questionnaires and interviews focusing on functioning and disability and quality of life. If the items or concepts within questionnaires and interviews were not specified in the publication, attempts were made to obtain them by checking references, or conducting database and internet searches.

In Step 3, the concepts contained in all the outcome variables were determined, and linked to the most specific ICF category possible by two independent health professionals according to linking rules developed for this purpose (A. Cieza et al., 2005). In the case of questionnaires and interviews, the items were extracted, the concepts contained in them identified, and these were also linked to the ICF according to the same linking rules. If a concept of an outcome parameter was not represented by the ICF, it was coded as "not covered". For instance, "suicide attempts" were considered not to be covered by the ICF. Concepts referring the ICF domain of personal factors were coded as such; however, because personal factors are not enumerated in the ICF, no specific ICF codes were attributed to them.

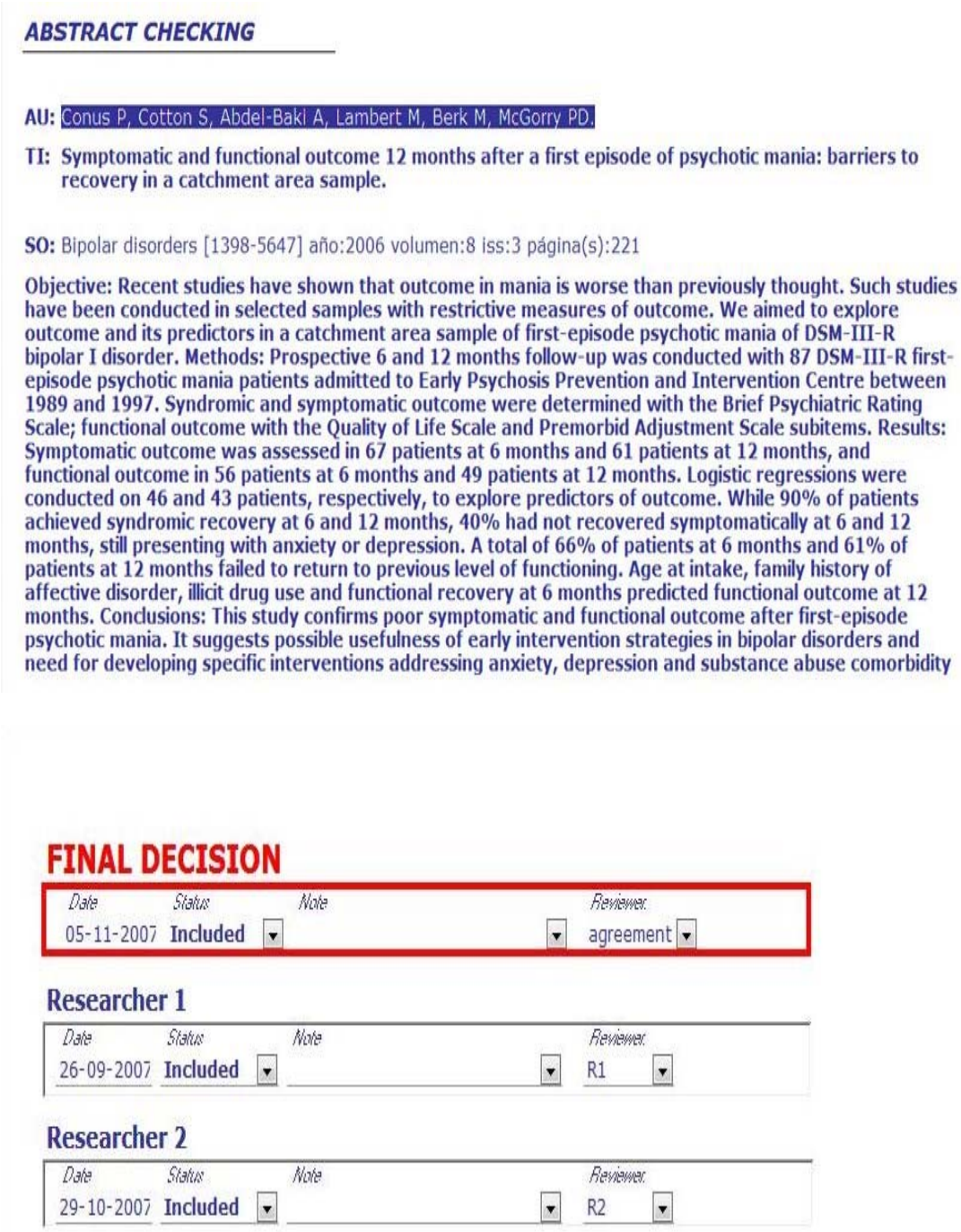
Study Population

Articles published between 2000-2006 in English language meeting the following eligibility criteria were selected: 1) human population; 2) age ≥ 18; 3) individuals with main diagnosis Bipolar Disorder type I or II or conditions on the Bipolar Disorder Spectrum at the beginning of the data collection; and 4)

sample size >10 participants. Regarding the study design, randomized controlled trials, randomized clinical trials, clinical controlled trials, cross-sectional studies, longitudinal observational studies, and qualitative studies were included. In case of multiple publications of the same data, the article published in the journal with the highest impact factor was considered. In the case of multiple publications in the same journal (e.g. follow-up study), the most recent one entered the study. Reviews (or topic overviews), meta-analyses, comments, letters, editorials, guidelines, conference reports, book chapters and dissertations were excluded.

Study Materials

Publications were retrieved from Medline (via Pubmed) and PsycINFO online search engines. All abstracts were stored in an Access Database, that was also used to check the eligibility of the articles. Figure 4 shows the database that was developed for abstract checking of the papers.



ABSTRACT CHECKING

AU: Conus P, Cotton S, Abdel-Baki A, Lambert M, Berk M, McGorry PD.

TI: Symptomatic and functional outcome 12 months after a first episode of psychotic mania: barriers to recovery in a catchment area sample.

SO: Bipolar disorders [1398-5647] año:2006 volumen:8 iss:3 página(s):221

Objective: Recent studies have shown that outcome in mania is worse than previously thought. Such studies have been conducted in selected samples with restrictive measures of outcome. We aimed to explore outcome and its predictors in a catchment area sample of first-episode psychotic mania of DSM-III-R bipolar I disorder. Methods: Prospective 6 and 12 months follow-up was conducted with 87 DSM-III-R first-episode psychotic mania patients admitted to Early Psychosis Prevention and Intervention Centre between 1989 and 1997. Syndromic and symptomatic outcome were determined with the Brief Psychiatric Rating Scale; functional outcome with the Quality of Life Scale and Premorbid Adjustment Scale subitems. Results: Symptomatic outcome was assessed in 67 patients at 6 months and 61 patients at 12 months, and functional outcome in 56 patients at 6 months and 49 patients at 12 months. Logistic regressions were conducted on 46 and 43 patients, respectively, to explore predictors of outcome. While 90% of patients achieved syndromic recovery at 6 and 12 months, 40% had not recovered symptomatically at 6 and 12 months, still presenting with anxiety or depression. A total of 66% of patients at 6 months and 61% of patients at 12 months failed to return to previous level of functioning. Age at intake, family history of affective disorder, illicit drug use and functional recovery at 6 months predicted functional outcome at 12 months. Conclusions: This study confirms poor symptomatic and functional outcome after first-episode psychotic mania. It suggests possible usefulness of early intervention strategies in bipolar disorders and need for developing specific interventions addressing anxiety, depression and substance abuse comorbidity

FINAL DECISION

Date	Status	Note	Reviewer
05-11-2007	Included		agreement

Researcher 1

Date	Status	Note	Reviewer
26-09-2007	Included		R1

Researcher 2

Date	Status	Note	Reviewer
29-10-2007	Included		R2

Figure 4: Database used to check eligibility of abstracts

On step 2 "extraction of outcome variables" a different database was used to extract the variables in study in the different articles. This database was also created in Microsoft Access and is shown in Figure 5. In step 3 data was linked to the ICF using Microsoft Excel.

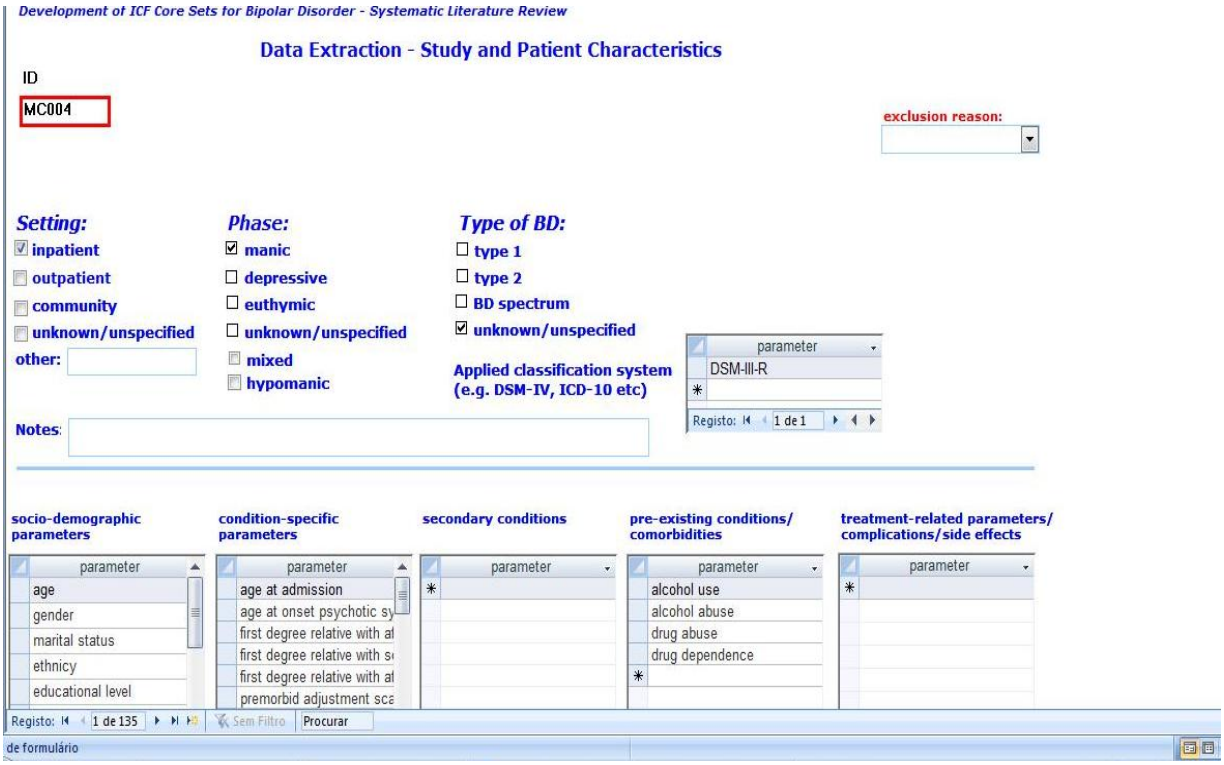


Figure 5: Database used to extract the data contained in the selected articles

Sample Size

The number of studies that was finally included in the study was determined by the previously described data collection procedures and depended on a) the number of articles obtained from the automatic search and b) the number of those articles that fulfilled the eligibility criteria.

Data Analysis

Descriptive statistics were used to examine the frequency with which standardized diagnostic instruments, as well as questionnaires to assess functioning and disability and QoL, were used. These frequency analyses were performed for all the studies in general and differentiating between study types: intervention and observational. Pharmacological, non-pharmacological and studies with a combination of both intervention types were differentiated.

Descriptive statistics were also used to examine the frequency of ICF categories linked to the concepts contained in the outcome variables. ICF categories assigned repeatedly in a study were counted only once. Frequency analyses were performed for all the studies in general and differentiating between interventional and observational studies and for the different intervention types, following the same methodology used to analyze questionnaires and instruments. The 95% confidence intervals (CI) for the reported frequencies are also reported to explore possible differences. The difference between frequencies is considered significant when the CI of the frequencies do not overlap.

ICF categories are presented on the second-level of the classification. If a concept of an outcome parameter was linked to a third- or fourth-level ICF

category, the overlying second-level category was considered. Since the ICF is organized in a hierarchical scheme, more specific lower-level categories share the attributes of less specific higher-level categories (Finger, Cieza, Stoll, Stucki, & Huber, 2006). ICF categories with a frequency equal or greater than 10% are shown.

Quality Assurance Procedures

To assure quality of data, researchers involved in the data collection received training on the ICF, the ICF linking rules and familiar with the inclusion and exclusion criteria that were applied. Furthermore, abstract check and linking of data was performed by two researchers independently (one of them being the author of this document). Consensus between the two independent researchers was used to decide which ICF category should be linked to each item or concept. The inter-rater reliability between the two researchers in the present study was calculated using the Kappa coefficient based on the Bias Corrected Percentile Method.

b) Qualitative Study

Study Design

Data on the individual perspective on BD was collected through direct interviewing of adults suffering from BD type I and II. Participants were referred by their psychiatrist and presented with the option of accepting or refusing to collaborate. Conditions of participation as well as the objective of the study were explained in written and oral form by interviewers and consent for voice and video recording was also collected in written form. All personal information

gathered remained confidential. This study was approved by the Ethics Committee of the University Hospital "La Princesa" in Madrid.

The interviews were conducted in a private room at the hospital and included open-ended questions about the BD.

Study Population

Inclusion criteria involved individuals diagnosed with BD type I and II following the CID-10 (World Health Organization, 1996) or the DSM-IV (American Psychiatry Association, 1994a) criteria that were euthymic at the time of the interview according to medical judgment and followed at the Psychiatry unit of the La Princesa hospital. Patients should be at least 18 years old to be included in the study and have no further diagnoses of mental illness. All patients were required to sign a written consent form prior to the interview. The sampling of patients followed the maximum variation strategy based on two criteria: form of BD and age group.

Study Materials

A semi-structured interview was applied, containing the Spanish version of the following 5 open-ended questions on functioning.

- According to your opinion, and in regard to your health condition, is there anything in your body and mind that doesn't work the way it should?
- Thinking about your body (and mind), with which part would you say you have problems?
- Speaking about your daily life: what problems do you face? Which of your activities and shores have become difficult for you?

- Regarding your environment and surroundings, can you identify aspects that a) serve you as help or support and b) constitute difficulties and make your life with the disorder harder?

- Can you tell me about the way you deal with your condition? Is there something about the way you think or act that helps you or makes it difficult for you to deal with BD?

In addition to these questions participants were invited to rate in a scale from 1 to 10 the overall impact bipolar disorder has in their lives as well as their general health. Demographic and clinical data collected on the participants included age, gender, level of studies, marital status, living condition (people with whom the participant lives), profession and working situation and type of bipolar disorder.

Sample Size

The number of interviews was determined by saturation point. In the present study saturation was considered when two interviews in a row did not reveal new information.

Data Analysis

Interviews were transcribed verbatim. The protocols were then read one first time to allow identification of general topics and themes. Next, relevant concepts contained in the answers given by the participants were extracted and the information gathered was linked to the ICF categories by a trained researcher according to the published linking rules (Alarcos Cieza, Szilvia

Geyh, Somnath Chatterji, Nenad Kostanjsek, Bedirhan Ustun, et al., 2005) and relative and absolute frequencies of each of the ICF categories were calculated. Socio-demographical data and clinical data, including diagnosis of a bipolar spectrum disorder, were collected from the patient or from his or her doctor. Statistical analysis included descriptive measures of socio-demographic, clinical and functioning variables. Descriptive statistics were also used to examine the frequency of ICF categories linked to the concepts contained in the interviews. ICF categories assigned repeatedly in a protocol were counted only once.

ICF categories are presented on the second-level of the classification. If a concept was linked to a third- or fourth-level ICF category, the overlying second-level category was considered. Since the ICF is organized in a hierarchical scheme, more specific lower-level categories share the attributes of less specific higher-level categories (Finger, et al., 2006). Analyses were performed with SPSS (v.16) ("SPSS," 2007) and Microsoft® Excel 2003 (Microsoft Excel Professional, 2003).

c) Expert Survey

Study Design

An expert survey was conducted in our study. An expert survey tries to identify all aspects that are relevant in a specific field of research. The inclusion of experts on a specific field is based on the assumption that experts have an advantage in information and knowledge about that topic. This maximizes the number and range of ideas and opinions gathered while minimizing the number of persons needed to ask. The online form of a survey makes it possible to

collect data from around the world in a fast and confidential way, reducing costs and increasing the number of participants taking part on the study.

In a first step, an e-mail was sent to selected experts including information about the study and asking them for their participation. Participants willing to participate are required to express their interest by filling in a personal data form, including general information such as name, profession, affiliation and e-mail address. All experts, who agreed to participate, were included in the study. In a second step, an e-mail was sent to the participants containing the instructions on how to participate on the survey. Participants also received an e-mail containing their personal password and username to enter the survey website. The experts should then complete the survey and the answers obtained can then be linked to the ICF based on established linking rules (A. Cieza et al., 2002a; Alarcos Cieza, Szilvia Geyh, Somnath Chatterji, Nenad Kostanjsek, Bedirhan Üstün et al., 2005) by the project team members. To assure confidentiality each participant received a personal username and password to access the survey website and was blind to the answers of the others. Participants were identified in the data bases with an ID number, so that no personal identifiers were included in the files.

Study Population

Since the ICF was developed to facilitate communication between different groups of people and to be used globally, the aim was to include experts from the following WHO regions: Eastern Mediterranean, South-East Asia, Western Pacific, The Americas, Africa and Europe. It was planned to perform an expert survey with psychologists, psychiatrists, nurses and social workers. While

including a wide range of participants, quality had to be ensured by selecting only participants with a proven expertise and experience in the research field. Therefore, an expert should meet following inclusion criteria in our study:

1) health professional with the necessary qualification (psychiatrist, psychologist, nurse or social worker)
2) experienced in the treatment of individuals with BD for at least five years
3) fluent in English to contribute to the survey

The experts were selected in two successive steps. In the first step of the recruitment, international organizations in the field of BD were identified. Representatives from the identified organizations, as well as representatives from associated organizations in this project were contacted and asked to name experts. A pool consisting of all experts (total sample) who fulfilled the selection criteria was created. Experts selected were contacted via e-mail and asked if they would like to participate in our expert survey. All experts who gave their agreement entered our study.

Study Materials

In the expert survey an open-ended, self-developed questionnaire was used regarding problems important to patients with BD:

1. Please list in the following lines body functions in which patients with BD have problems.
2. Please list in the following lines body structures in which patients with BD have problems.

3. Please list in the following lines activities and participation patients with BD have problems with.
4. Please list in the following lines environmental factors having a positive and/or negative influence on the problems of patients with BD.
5. Please list in the following lines personal factors that have a positive and/or negative influence on the problems of patients with BD.

The survey was hosted at a website (http://icfresearch.avile.de). An image of the welcome page is showed in Figure 6

Figure 6: Image of the Welcome Page of the Online Survey

Sample Size

The expert survey included psychiatrists, psychologists, nurses and social workers from six different WHO regions. In a first step, a pool of expert was

created. This expert pool is stratified by health profession and WHO region. When selecting the participants, we considered that the survey should be representative for each health profession and each WHO region. On the first step of the recruitment phase e-mails we sent to all the experts identified. Also, the Bipolar Disorders Association was contacted and forwarded the invitation to participate to all its members worldwide. All participants that accepted to participate where given the proper instructions and requested to fill in the questionnaire. The number of participants was determined by the availability of the contacted experts.

Data Analysis

In a first step, answers of the expert survey were read through to get an overview over the collected data. In a second step, the theme that dominates an answer was determined. In the third step, the concepts contained in the theme were identified. A theme can contain more than one concept. Data extraction was performed separately by two health professionals. Initial disagreement was solved after discussion between both. If the disagreement remains a third person was consulted. In the final fourth step, every concept was linked to ICF categories according to published linking rules (A. Cieza et al., 2002b; Alarcos Cieza, Szilvia Geyh, Somnath Chatterji, Nenad Kostanjsek, Bedirhan Üstün, et al., 2005). Linked ICF categories were defined as relevant concepts of functioning in patients with BD from the expert perspective (Figure 7).

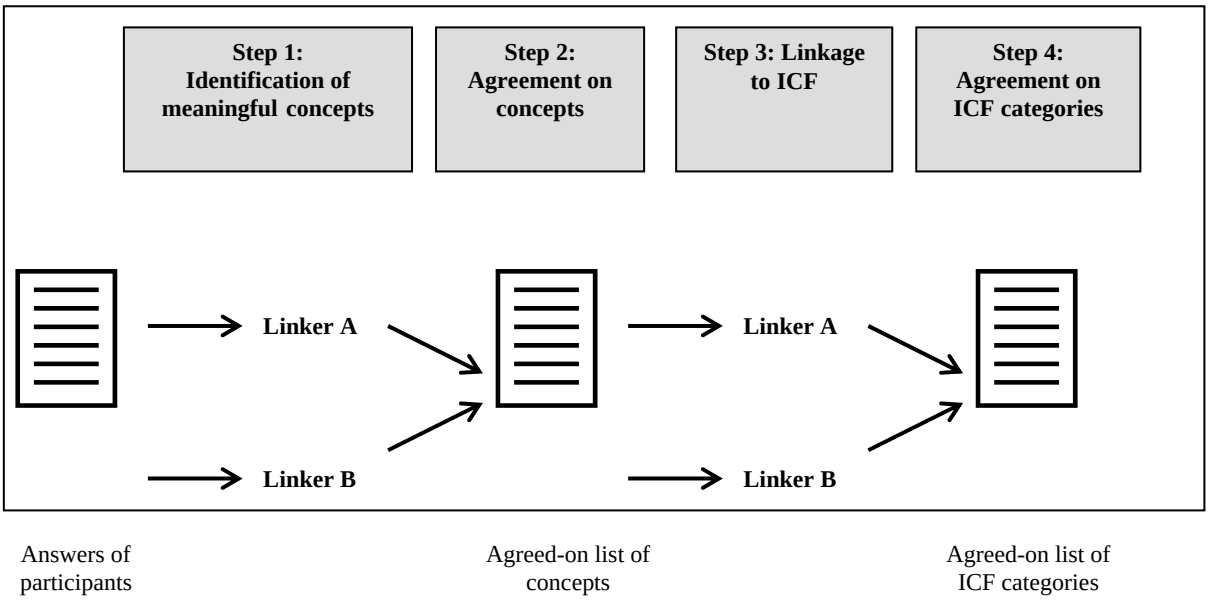


Figure 7: Linking Process

Quality Assurance Procedures

While including a wide range of participants, quality had to be ensured by selecting only participants with a proven expertise and experience in the research field. In our study, an expert is defined as a health professional with the necessary qualification experienced in the treatment of patients with BD at least for five years. In addition, the health professional should be fluent in English to contribute to the survey.

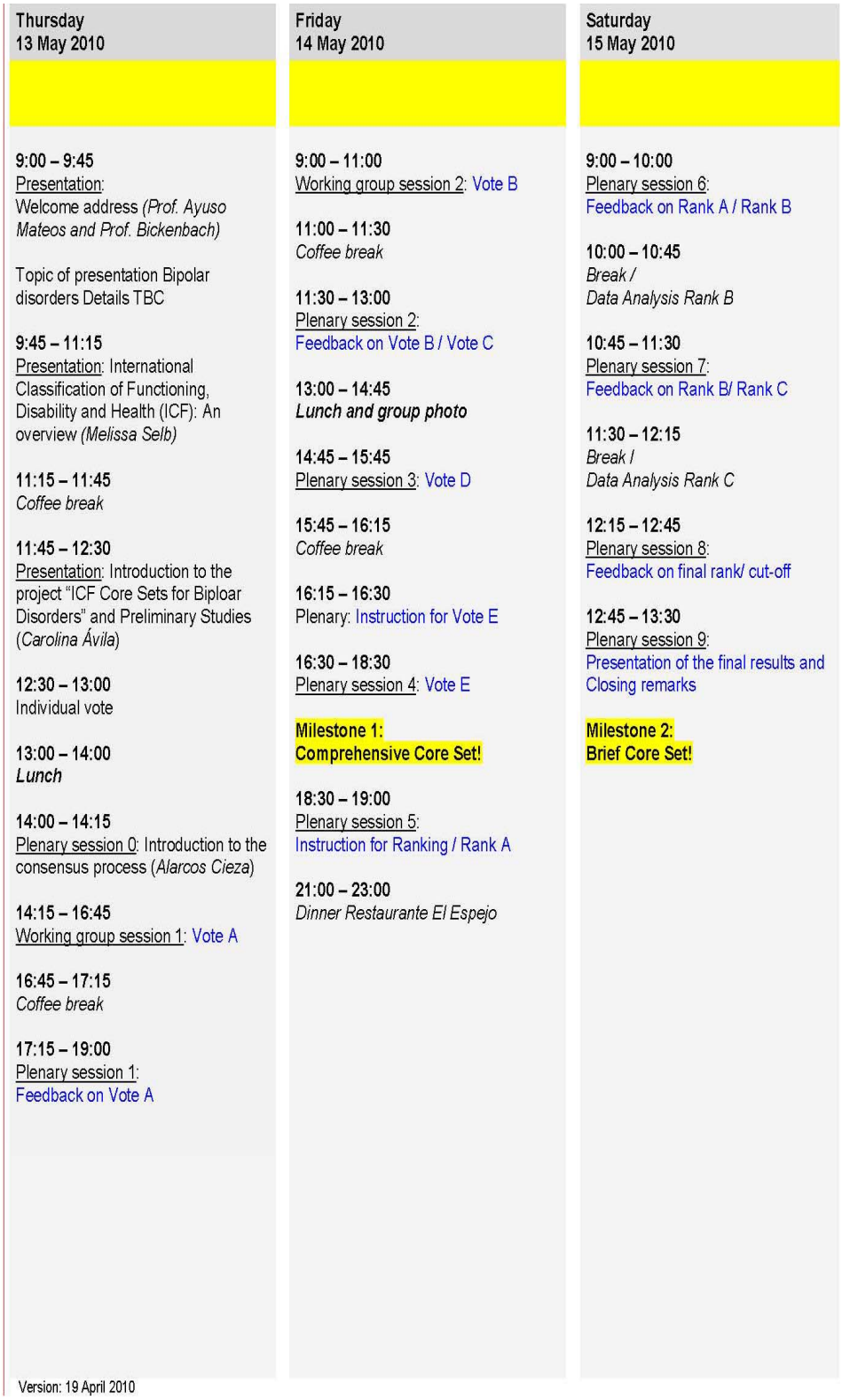
When selecting the participants, we consider that the survey should be representative for each health profession and each WHO region.

To assure the data quality during the data extraction process, the data extraction is performed separately by two health professionals who are experts in the ICF and in the application of the linking rules.

d) ICF Core Sets International Consensus Conference for BD

Study Design

The ICF Core Set Consensus Conference was conducted in Madrid from the 13th to the 15th May 2010 at the University Autónoma in Madrid. Figure 8 shows the timetable of the conference.



Thursday 13 May 2010	Friday 14 May 2010	Saturday 15 May 2010
9:00 – 9:45 Presentation: Welcome address *(Prof. Ayuso Mateos and Prof. Bickenbach)* Topic of presentation Bipolar disorders Details TBC **9:45 – 11:15** Presentation: International Classification of Functioning, Disability and Health (ICF): An overview *(Melissa Selb)* **11:15 – 11:45** *Coffee break* **11:45 – 12:30** Presentation: Introduction to the project "ICF Core Sets for Biploar Disorders" and Preliminary Studies (*Carolina Ávila*) **12:30 – 13:00** Individual vote **13:00 – 14:00** ***Lunch*** **14:00 – 14:15** Plenary session 0: Introduction to the consensus process (*Alarcos Cieza*) **14:15 – 16:45** Working group session 1: Vote A **16:45 – 17:15** *Coffee break* **17:15 – 19:00** Plenary session 1: Feedback on Vote A	**9:00 – 11:00** Working group session 2: Vote B **11:00 – 11:30** *Coffee break* **11:30 – 13:00** Plenary session 2: Feedback on Vote B / Vote C **13:00 – 14:45** ***Lunch and group photo*** **14:45 – 15:45** Plenary session 3: Vote D **15:45 – 16:15** *Coffee break* **16:15 – 16:30** Plenary: Instruction for Vote E **16:30 – 18:30** Plenary session 4: Vote E **Milestone 1:** **Comprehensive Core Set!** **18:30 – 19:00** Plenary session 5: Instruction for Ranking / Rank A **21:00 – 23:00** *Dinner Restaurante El Espejo*	**9:00 – 10:00** Plenary session 6: Feedback on Rank A / Rank B **10:00 – 10:45** *Break /* *Data Analysis Rank B* **10:45 – 11:30** Plenary session 7: Feedback on Rank B/ Rank C **11:30 – 12:15** *Break /* *Data Analysis Rank C* **12:15 – 12:45** Plenary session 8: Feedback on final rank/ cut-off **12:45 – 13:30** Plenary session 9: Presentation of the final results and Closing remarks **Milestone 2:** **Brief Core Set!**

Version: 19 April 2010

Figure 8: ICF Consensus Conference Schedule

The training of the participants focused on both the ICF and the data from the preparatory studies. Therefore, the conference started with a half-day training workshop in which all participants were first familiarized with the ICF framework and classification. Participants were provided with summary sheets containing the ICF categories identified during the preparatory studies and an ICF book in which they could look up the description of the categories. The participants were informed about how the list of categories has been developed, i.e., about the evidence from the preparatory studies. In the plenary training session, the experts were also instructed to cover the prototypical spectrum of problems generally encountered in individuals with BD, without including co-morbidities and medical complications. The ICF Core Set categories were identified in an iterative decision-making process. Figure 9 shows the consensus process.

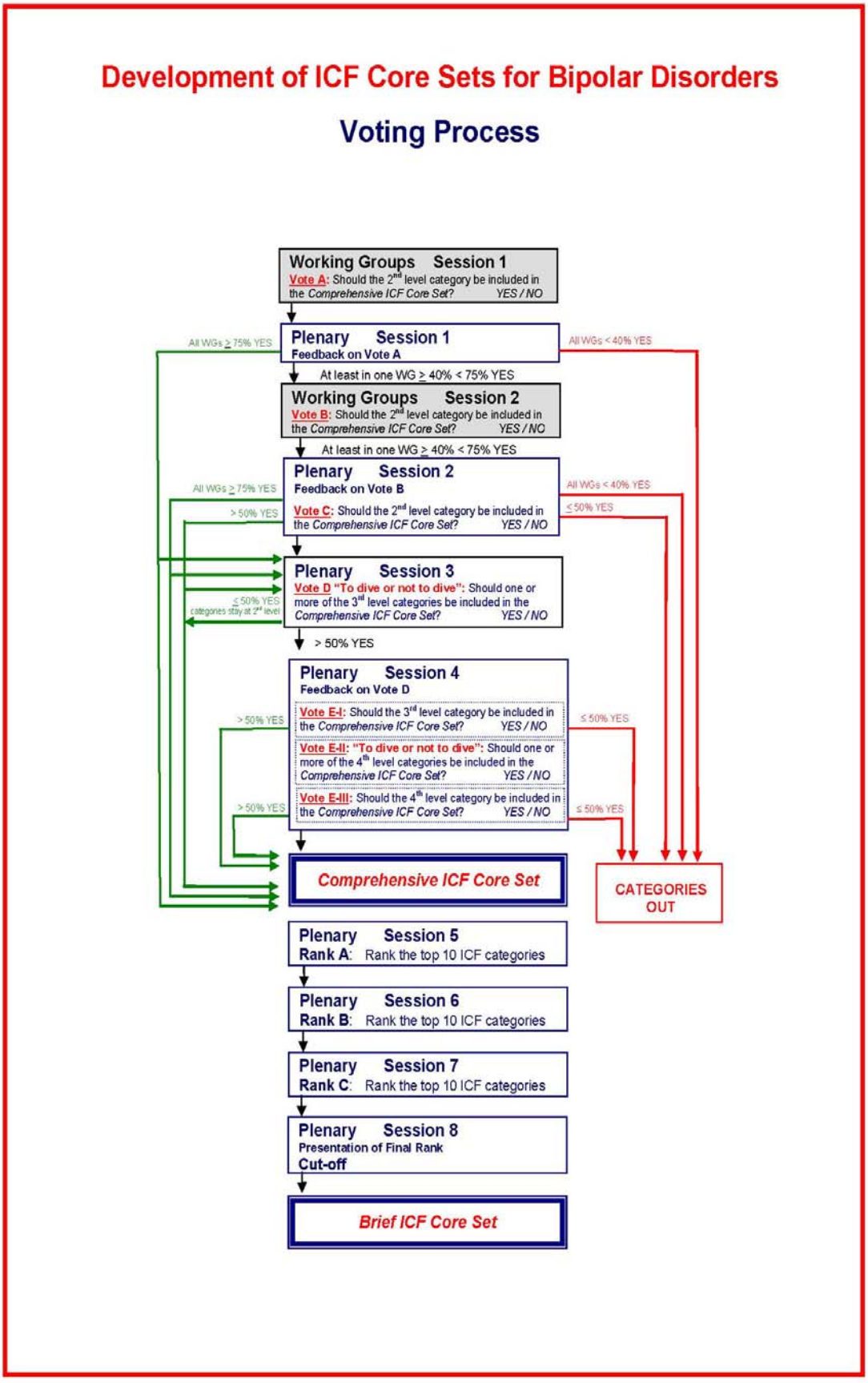


Figure 9: Voting Process

Two different kinds of sessions took place during the consensus process: a Condition Group session and a Working Group session. In the Condition Group session, all experts worked together while in the Working Group session the experts worked separately in their Working Groups. The main purpose of the Working Group sessions was to enable the participants to vote on each ICF category and to gather pros and cons for the selection of an ICF category. The main purpose of the Condition Group session was to enable the participants to obtain feedback from the other groups concerning the pros and cons for the selection on the controversial categories. ICF categories which are either clearly relevant or irrelevant according to preset decision rules depicted in Figure 9 were excluded from the discussion in the Condition Group. This enabled participants to focus on the remaining controversial categories. The decision-
-making process consisted of two major parts.

In the first part the experts were requested to select ICF categories for the Comprehensive ICF Core Set for BD, i.e., the list of ICF categories long enough to describe the prototypical spectrum of functioning and health of individuals with BD. But at the same time the Comprehensive ICF Core Set for BD had to be short enough to be practical in comprehensive, multidisciplinary assessments. Until Condition Group session 2 inclusively, the experts decided on the 2nd-level categories. From Working Group session 3 to Condition Group session 4, the experts decide whether "to dive or not to dive", i.e., on the 3rd- and 4th-level categories to be included in the Comprehensive ICF Core Set for BD. The experts were instructed to include a 3rd- or a 4th-level category only if the additional specification yielded by that category is essential to describe the

prototypical spectrum of limitations in functioning and health encountered in individuals with BD.

In the second part of the decision-making process the experts were requested to select from the 2nd-level ICF categories included in the Comprehensive ICF Core Set for BD lists of ICF categories long enough to describe the prototypical spectrum of functioning and health of individuals with BD. But at the same time the so-called Brief ICF Core Set for BD should be short enough to be feasible in clinical studies. This required a two-round ranking exercise followed by a final vote.

In the first ranking exercise, the experts individually ranked the 10 most essential 2nd-level categories to be included in the Brief ICF Core Set for BD in their order of importance for each ICF component (Body Functions, Body Structures, Activities and Participation, and Environmental Factors). After the feedback on the first ranking exercise the experts ranked individually the 10 most essential 2nd-level categories for each ICF component in a second ranking. For the final vote and after having defined a common ranking order for the ICF categories, the experts decided on their own how many 2nd-level ICF categories per ICF component they wanted to have included in the Brief ICF Core Set for BD. In a Condition Group session all experts voted on whether they wanted to have more than one category, more than two categories, more than three categories, etc. included in the Brief ICF Core Set for BD.

Study Population

The recruitment strategy had to balance the needs for expertise and international and professional representation and the need for a feasible and affordable decision-making process. Therefore, (1) clinicians involved in the (2)

opinion leaders in the different health conditions were identified and invited, and (5) experts in the fields of functioning and health, quality of life and public health from developing countries were contacted and invited to the conference. This strategy ensures broad international representation and clinical expertise among the participants. In addition, it had to be considered that 1/3 of the participants were from Spain, 1/3 from Europe and 1/3 from overseas. The participants were also invited taking into consideration that different professions such as psychiatrists, psychologists, nurses and social workers should to be represented at the conference.

Study Materials

The experts were provided with the data obtained from the preliminary studies that were described in the previous sections and from an empirical study that was conducted with bipolar patients in Madrid and Barcelona and that allowed us to include the clinical perspective (see section "other sources of information"). Besides from presenting the data to the large group, all experts were provided with a handout containing the identified categories (see annexes). Data collected at the working group sections was entered into a database, as showed in Figure 10.

	B	C	D	E	G	I	K	M	N	O
1	A_WG1	BD		Description	Empir. Study	Expert Survey	System. Review	Qualitat. Study	Check and Save	
2					%	%	%	n	Vote A	
3	ICF code			ICF title	n = 128	n = 68	n = 109	15	WG 1	
4	2 level	3 level	4 level						"yes"	N
5	b110			Consciousness functions	2	3	2	3		
7	+b114			Orientation functions	15	3				8
8	b114			Orientation functions	15	3				
9		b1140		Orientation to time		1				
10		b1141		Orientation to place						
11		b1142		Orientation to person						
12			b11420	Orientation to self		1				
13			b11421	Orientation to others						
15	b117			Intellectual functions	5	4	29	3		8
17	b122			Global psychosocial functions		4	5			8
19	+b126			Temperament and personality functions	41	34	24	11		8
20	b126			Temperament and personality functions	38	12	6	7		
21		b1260		Extraversion	31	4		1		
22		b1261		Agreeableness		3	3	1		
23		b1262		Conscientiousness		1		1		
24		b1263		Psychic stability		19	17	2		
25		b1264		Openness to experience		1		2		
26		b1265		Optimism		4	4	4		
27		b1266		Confidence		3	2	2		
28		b1267		Trustworthiness		3		2		
30	+b130			Energy and drive functions	67	65	18	10		8
31	b130			Energy and drive functions	67	15	2	1		
32		b1300		Energy level		37	9	4		
33		b1301		Motivation		15	3	8		
34		b1302		Appetite		26	3	4		
35		b1303		Craving		13	1	1		

Figure 10: Part of the database used to store the data collected in the working groups

Sample Size

Effort was placed in recruiting between 21 and 27 experts to attend the conference. From these 21 to 27 experts 1/3 should come from Spain, 1/3 from European countries other than Spain and 1/3 from overseas.

Data Analysis

After each working group sessions was put together and percentages of positive votes for inclusion of a category were calculated by working group and for the total of the participants. During plenary season 3 (vote D) where participants would vote whether to dive or not to dive frequency of positive answers were also calculated immediately after the vote. After the ranking sessions data from the individual participants were also compilated and a general rank was established.

Quality Assurance Procedures

Group assistants observed the discussions and voting process and data recording for quality assurance. Votes were counted by two persons. Group leaders and group assistants were trained in use and application of the ICF and in conducting group processes prior to the beginning of the conference. Owing to the importance of immediate feedback on the voting results during the whole decision-making and consensus process, the data entry of the voting and ranking process, respectively, was performed continuously. In order to avoid bias by recording or typing errors data registration was carried out online in prepared structured formats with predefined plausibility ranges.

e) Other sources of information[1]

In addition to the previous studies, data from an empirical study performed earlier by members of our team within the framework of the European Measuring Health and Disability in Europe (MHADIE) project (6th framework) were taken into account in the development of ICF Core Sets for Bipolar Disorders and presented to the experts at the ICF Core Sets International Consensus Conference. The objective of the empirical cross-sectional study was to describe functioning and health of patients with BD using the extended ICF Checklist. In this study 128 patients were administered the ICF-checklist and other standardized questionnaires to assess functioning and clinical scales by trained health professionals in different time-points. However, the results reported here are based on the baseline assessments. The data collection was performed at the University Hospital La Princesa in Madrid and at the Hospital Clinic in Barcelona. All patients met DSM-IV criteria for bipolar I or disorder and were euthymic. The remission criteria were; prospectively-assessed euthymia, lasting at least 6 months, with scores of 8 or less on the Hamilton Depression Rating Scale (HDRS) (Hamilton, 1960) and 6 or less on the Young Mania Rating Scale (YMRS) (Young, Biggs, Ziegler, & Meyer, 1978). Mentally retarded patients were excluded as well as those patients who had received the psychoeducation program in the last two years. All patients provided written informed consent. Ethical approval for the study was granted by the Ethics Committees of the two hospitals. Study measures included socio-demographic variables, such as age, gender, educational level and marital status. Moreover,

[1] Data mentioned as "other sources of information" is submitted for publication as "Sanchez-Moreno, J; Martínez-Aran, A.; Gadelrab, H; Cabello, M; Torrent, C; Bonnin, C; Ferrer, M, Leonardi, M; Aysuo-Mateos, JL; Vieta, E. *The role and impact of contextual factors on functioning in patients with bipolar disorder.*"

clinical variables were collected as part of the Bipolar Disorders Program protocol of the Hospital Clinic of Barcelona and the same protocol was used in the Hospital Universitario de la Princesa. The clinical variables included in this study were the number and type of episodes, age at onset of the illness, duration of the illness, number of hospitalizations, number of suicide attempts, family history of psychiatric disorders, history of psychotic symptoms, diagnostic type I or II, seasonal pattern, rapid cycling, YMRS and HDRS scores, Comorbidities (Axis I, II and III). Additional information was obtained through contextual factors, such as cognitive dysfunctional schemas, evaluated with the Dysfunctional Attitudes Scale (DAS) (de Graaf, Roelofs, & Huibers, 2009) were measured by using a short version (21 self-report items). DAS was used to assess dysfunctional beliefs of bipolar patients; and social support perceived by the patient, using the Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet, Powell, Farley, Werkman, & Berkoff, 1990). Interviewers were carefully trained before the study started and there was a computer-assisted data check during the study entry. Raw data was also carefully checked.

For the purpose of the present project we were interested in the frequency of appearance of the different ICF categories that were selected in the assessment of these patients. This allowed us to include data from a forth perspective: the perspective of the health professional working with bipolar patients. Patients on the one hand and clinicians and health professionals on the other have expertise that pertains to the same realities, namely disease and its consequences, but from very different perspectives. Patients are experts in their own experience of disease and its consequences, and clinicians and health professionals are experts in the treatment of disease and its

limitations and participation restrictions, and to prevent new symptoms and disabilities from developing. Thus, the study of the question of whether the ICF contains the intervention goals of clinicians and health professionals when treating patients with different health conditions can very much contribute to addressing the question of its content validity.

Only in the event that the answer is affirmative can one assume that the ICF will achieve the acceptance and recognition necessary for future implementation in medicine. Medical disciplines are usually defined based on the targets of their interventions, i.e. the disease(s), the organ system(s) and/or the population(s) that they treat. The same applies to the definition of other health professions, such as physical therapy, occupational therapy or psychology. They are also defined based on the goals of the interventions applied by the health professionals belonging to those professions. Presumably, clinicians and health professionals will accept the ICF as a common classification if they perceive that is represents their core competencies.

From the data on the 128 individuals with bipolar disorders, 112 ICF categories at the second level were obtained, also including the more specific third – and forth levels. From these 33 belong to the ICF domain "Body Functions", 5 to "Body Structures", 47 to "Activities and Participation" and 27 to "Environmental Factors". Table 3 shows the relative frequencies of the ICF categories that were obtained.

Table 3: Relative frequency of the ICF categories obtained from the clinical data from BD patients

ICF Core	*ICF Category*	*Frequency*	*% (n=128)*
e110	Products or substances for personal consumption	119	93
e310	Immediate family	118	92
b152	Emotional functions	111	87
e410	Individual attitudes of immediate family members	111	87
b144	Memory functions	101	79
e320	Friends	99	77
e355	Health professionals	94	73
b140	Attention functions	92	72
d230	Carrying out daily routine	92	72
e420	Individual attitudes of friends	87	68
b130	Energy and drive functions	86	67
b164	Higher-level cognitive functions	85	66
d220	Undertaking multiple tasks	85	66
e580	Health services, systems and policies	85	66
d240	Handling stress and other psychological demands	80	63
e450	Individual attitudes of health professionals	77	60
d640	Doing housework	73	57
d770	Intimate relationships	72	56
d175	Solving problems	70	55
d850	Remunerative employment	68	53
d845	Acquiring, keeping and terminating a job	65	51
b280	Sensation of pain	64	50
d570	Looking after one's health	63	49
e325	Acquaintances, peers, colleagues, neighbours and community members	63	49
d350	Conversation	61	48
d910	Community life	61	48
b160	Thought functions	59	46
d177	Making decisions	59	46
d720	Complex interpersonal interactions	59	46
d730	Relating with strangers	59	46
d430	Lifting and carrying objects	58	45
d750	Informal social relationships	58	45
d920	Recreation and leisure	58	45
b330	Fluency and rhythm of speech functions	56	44
d870	Economic self-sufficiency	56	44
b134	Sleep functions	54	42
b126	Temperament and personality functions	53	41
b147	Psychomotor functions	50	39
d630	Preparing meals	46	36
d310	Communicating with - receiving - spoken messages	43	34
d740	Formal relationships	42	33

d760	Family relationships	41	32
e460	Societal attitudes	40	31
d620	Acquisition of goods and services	35	27
d210	Undertaking a single task	34	27
d510	Washing oneself	34	27
d330	Speaking	33	26
b172	Calculation functions	32	25
e330	People in positions of authority	31	24
d450	Walking	30	23
d520	Caring for body parts	30	23
e570	Social security services, systems and policies	30	23
e340	Personal care providers and personal assistants	29	23
b530	Weight maintenance functions	28	22
d660	Assisting others	28	22
d710	Basic interpersonal interactions	28	22
b640	Sexual functions	26	20
e440	Individual attitudes of personal care providers and personal assistants	22	17
d150	Learning to calculate	21	16
d540	Dressing	20	16
d550	Eating	20	16
b114	Orientation functions	19	15
d440	Fine hand use	19	15
b210	Seeing functions	18	14
d860	Basic economic transactions	18	14
e225	Climate	18	14
d475	Driving	15	12
b156	Perceptual functions	14	11
d470	Using transportation	13	10
e115	Products and technology for personal use in daily living	12	9
b765	Involuntary movement functions	11	9
e455	Individual attitudes of health-related professionals	11	9
b620	Urination functions	10	8
e125	Products and technology for communication	9	7
e240	Light	9	7
e590	Labour and employment services, systems and policies	8	6
d115	Listening	7	5
d335	Producing nonverbal messages	7	5
d930	Religion and spirituality	7	5
b117	Intellectual functions	6	5
e360	Other professionals	6	5
b167	Mental functions of language	5	4
d315	Communicating with - receiving - nonverbal messages	5	4
e465	Social norms, practices and ideologies	5	4
b710	Mobility of joint functions	4	3
s750	Structure of lower extremity	4	3

d110	Watching	4	3
b110	Consciousness functions	3	2
b230	Hearing functions	3	2
b555	Endocrine gland functions	3	2
s630	Structure of reproductive system	3	2
b430	Haematological system functions	2	2
b515	Digestive functions	2	2
d465	Moving around using equipment	2	2
d830	Higher education	2	2
d950	Political life and citizenship	2	2
e120	Products and technology for personal indoor and outdoor mobility and transportation	2	2
e575	General social support services, systems and policies	2	2
b235	Vestibular functions	1	1
b410	Heart functions	1	1
b440	Respiration functions	1	1
b525	Defecation functions	1	1
b730	Muscle power functions	1	1
b735	Muscle tone functions	1	1
s730	Structure of upper extremity	1	1
s740	Structure of pelvic region	1	1
s760	Structure of trunk	1	1
d560	Drinking	1	1
d940	Human rights	1	1
e155	Design, construction and building products and technology of buildings for private use	1	1
e525	Housing services, systems and policies	1	1
e585	Education and training services, systems and policies	1	1

Most frequently measures "body functions" were "Emotional Functions" (87%) and b144 "Memory Functions" (79%). From the "Body Structures" domain s750 "'Structure of lower extremity" (3%) and "s630 "Structure of reproductive system" (2%) obtained the highest frequencies. Regarding the "Activities and Participation" domain d920 "Carrying out daily routine" (72%) and d220 "Undertaking multiple tasks" (66%) were highest selected. From the "Environmental Factors" e310 "Products or substances for personal consumption" (93%) and e310 "Immediate family" (92%) showed the highest frequency of appearance.

Results

Results by study

a) Systematic Literature Review

In Step 1, 864 studies were located using the electronic search strategy. Of these, 135 studies were preliminarily selected by review of abstracts, and 109 (13% of the retrieved studies) studies fulfilled the eligibility criteria based on screening the respective original papers. The most frequent exclusion criterion was "population type", which was applied to studies performed with minors (less than 18 years of age), when the studied sample included participants with a condition other than bipolar disorder and when there were less than 10 participants in the study. A total of 20593 persons participated in the 109 eligible studies, with the number of participants per study ranging 10 to 3557. The total sample across studies was equality split regarding gender, comprising 10250 females (50%). Mean age per study ranged from 22 to 59.

In 40% of the studies, participants had BDI; in 7%, BDII, and in 33% both. The remaining 20% of studies included adults with disorders in the bipolar spectrum or eligible subtypes of BD which were not specified in the article.

Of the studies, 71.56% were observational studies. For systematization reasons, observational studies were considered to include a) descriptive or observational cross-sectional studies, b) descriptive or observational longitudinal studies, c) cross-sectional psychomotor or diagnostic studies and d) longitudinal psychomotor or diagnostic studies. The remaining 31 studies (28.44%) described interventions conducted with BD individuals in the

framework of randomized clinical trials, controlled clinical trials, or other types intervention of studies.

Pharmacological therapy was the most frequently used intervention type, with an overall prevalence of 17.4% (19 studies). Pure non-pharmacological interventions were not found. Combined interventions were applied in 11% of the studies (12 studies).

In Step 2, 2642 clinical variables and 149 clinical measures were extracted. In addition, 36 instruments were retrieved, including questionnaires and assessment scales. Table 4 presents the frequency with which these outcome variables were used, considering different study and intervention types. The most frequently used instruments were the Hamilton Rating Scale for Depression (Hamilton, 1960) and the Young Mania Rating Scale (Young, et al., 1978). The clinical measures, including tests and non-paper based evaluations and rating scales for health professionals, having the highest frequency of appearance were the Global Assessment of Functioning (American Psychiatry Association, 1994b) and the Wechsler Adult Intelligence Scale (Wechsler, 1995)

.

Table 4: Frequency with which standardized diagnostic instruments were used, as well as questionnaires to assess functioning and disability and quality of life, considering different study and intervention types

		Study type									
		Interventional (N=31)							**Observational (N=78)**		**Total (N=109)**
		Pharmac (N=19)		Combined (N=12)		All (N=31)			All		
Instrument	HAM-D - Hamilton Rating Scale for Depression	9	47.37%	4	33.33%	13	41.94%		29	37.18%	42 38.53%
	YMRS - Young Mania Rating Scale	7	36.84%	1	8.33%	8	25.81%		28	35.90%	36 33.03%
	CGI - Clinical Global Impression	11	57.89%	0	0.00%	11	35.48%		5	6.41%	16 14.68%
	Beck-Rafaelsen Mania Rating Scale	3	15.79%	6	50.00%	9	29.03%		5	6.41%	14 12.84%
	SF-36 - Short-Form-36	3	15.79%	2	16.67%	5	16.13%		7	8.97%	12 11.01%
	BPRS - Brief psychiatric rating scale	4	21.05%	0	0.00%	4	12.90%		7	8.97%	11 10.09%
	BAS - Barners Akathisia Rating Scale	2	10.53%	2	16.67%	4	12.90%		5	6.41%	9 8.26%
Clinical Measure	GAF - Global Assessment of Functioning	9	47.37%	3	25.00%	12	38.71%		25	32.05%	37 33.94%
	WAIS - Wechsler Adult Intelligence Scale	2	10.53%	0	0.00%	2	6.45%		18	23.08%	20 18.35%
	Trail Making Test	2	10.53%	0	0.00%	2	6.45%		12	15.38%	14 12.84%
	WCST - Wisconsin Adult Card Sorting Test	2	10.53%	0	0.00%	2	6.45%		12	15.38%	14 12.84%
	National Adult reading test	1	5.26%	0	0.00%	1	3.23%		8	10.26%	9 8.26%
	SANS - Scale for assessment of negative symptoms	0	0.00%	0	0.00%	0	0.00%		8	10.26%	8 7.34%
	SCID - Structured Clinical Interview for DSM-IV	0	0.00%	0	0.00%	1	3.23%		7	8.97%	8 7.34%
	SCWF - Stroop Colour Work Interference Test	0	0.00%	0	0.00%	2	6.45%		6	7.69%	8 7.34%
	GAS - Global Assessment Scale	1	5.26%	0	0.00%	1	3.23%		6	7.69%	7 6.42%

Measures that appear at least in 5% of the articles

In Step 3, a total of 3191 concepts were extracted from the outcome variables. The Kappa coefficient for inter-rater agreement of linkage of these variables to the ICF was 0.63 (0.62; 065 CI). After linking and excluding duplicate concepts in the same publication, 2738 concepts were obtained; from this total, 2005 correspond to ICF categories. A total of 337 concepts were considered not covered by the ICF, 289 concepts were linked to ICF chapters although no second, third or fourth level ICF category seemed accurate enough to allow linking and 107 were linked to the component "Personal Factors". From the 2005 assignable concepts 1117 (55.71%) were linked to the component "Body Functions", 47 (2.34%) to "Body Structures", 579 (28.88%) to "Activities and Participation" and 262 (13.07%) to the 'Environmental Factors" chapter.

Overall, the concepts were linked to 145 different second-level ICF categories, also including the more specific third-, and fourth- level categories. Of these second-level ICF categories, 43 reached a frequency of at least 10%, 19 of them are body functions, 17 are activities and participation, and 7 are environmental factors. No body structure was contained in at least 10% of analyzed studies. Most frequently measured "body functions" were b152, "emotional functions" (93.58%), and b126, "temperament and personality functions" (73.39%); these were followed by b134, "sleep functions" (1.56%). Within the ICF component "activities and participation", the categories d350, "conversation" (45.85%), and d510, "washing oneself" (37.61%), showed the highest relative frequencies. Both e110, "products or substances for personal consumption" (67.89%) and e580, "health services, systems and policies" (67.89%), had the highest frequency of appearance within the environmental factors chapter; these were followed by category e355, "health professionals"

(22.02%). Although no body structures category appeared in at least 10% of the publications, the category with highest frequency of appearance is s110, "structure of the brain". Table 5 shows the relative frequency of the most used ICF categories (>=10%) linked to the concepts contained in the outcome variables for different study and intervention types. Results shown are summarized at the second-level of the classification.

Table 5: Relative frequency of the most used ICF categories (>=10%) linked to the concepts contained in the outcome variables for different study and intervention types

	ICF Category	Study type: Intervention									Observational			Total (05% CI) (N=109)		
		Pharmac (95% CI) (N=19)			Combined (95% CI) (N=12)			All (95% CI) (N=31)			All (95% CI) (N=78)					
Body functions																
b114	Orientation functions	4	21.05%	(2,7-39,4)	0	0.00%	(0-0)	4	12.90%	(1,1-24,7)	8	10.26%	(3,5-17,0)	12	11.01%	(5,1-16,9)
b117	Intellectual functions	4	21.05%	(2,7-39,4)	3	25.00%	(0,5-49,5)	7	22.58%	(7,9-37,3	27	34.62%	(24,1-45,2)	34	31.19%	(22,5-39,9)
b126	Temperament and personality functions	17	89.47%	(75,7-103,3)	9	75.00%	(50,5-99,5)	26	83.87%	(70,9-96,8)	54	69.23%	(59,7-80)	80	73.39%	(65,1-81,7)
b130	Energy and drive functions	11	57.89%	(35,7- 80,1)	7	58.33%	(30,4-86,2)	18	58.06%	(40,7-75,4)	42	53.85%	(42,8-64,9)	60	55.05%	(45,7-64,4)
b134	Sleep functions	16	84.21%	(67,8-100,6)	9	75.00%	(50,5-99,5)	25	80.65%	(66,7-94,6)	53	67.95%	(57,6-78,3)	78	71.56%	(63,1-80)
b140	Attention functions	10	52.63%	(30,2-75,1)	1	8.33%	(0-24)	11	35.48%	(18,6-52,3)	51	65.38%	(54,8-75,9)	62	56.88%	(47,6-66,2)
b144	Memory functions	5	26.32%	(6,5-46,1)	0	0.00%	(0-0)	5	16.13%	(3,2-29,1)	25	32.05%	(21,7-42,4)	30	27.52%	(19,1-35,9)
b147	Psychomotor functions	16	84.21%	(67,8-100,6)	7	58.33%	(30,4-86,2)	23	74.19%	(58,8-89,6)	51	65.38%	(54,8-75,9)	74	67.89%	(59,1-76,7)
b152	Emotional functions	19	100%	(100-100)	11	91.67%	(76-107,3)	30	96.77%	(90,5-103)	72	92.31%	(86,4-98,2)	102	93.58%	(89-98,2)
b156	Perceptual functions	14	73.68%	(53,9-93,5)	4	33.33%	(6,7-60)	18	58.06%	(40,7-75,4)	50	64.10%	(53,5-74,7)	68	62.39%	(53,3-71,5)
b160	Thought functions	16	84.21%	(67,8-100,6)	8	66.67%	(40-93,3)	24	77.42%	(62,7-92,1)	54	69.23%	(53,6-74,9)	78	71.56%	(63,1-80)
b164	Higher-level cognitive functions	12	63.16%	(41,5-84,9)	4	33.33%	(6,7-60)	16	51.61%	(34-69,2)	51	65.38%	(54,8-75,9)	67	61.47%	(52,3-70,6)
b167	Mental functions of language	2	10.53%	(0 -24,3)	0	0.00%	(0-0)	2	6.45%	(0 -15,1)	22	28.21%	(18,2-38,2)	24	22.02%	(14,2-29,8)
b280	Sensation of pain	6	31.58%	(10,7-52,5)	2	16.67%	(0 -37,8)	8	25.81%	(10,4-41,2)	13	16.67%	(8,4-24,9)	21	19.27%	(11,9-26,7)
b310	Voice functions	7	36.84%	(15,1-58,5)	1	8.33%	(0-24)	8	25.81%	(10,4-41,2)	28	35.90%	(26,2-47,6)	36	33.03%	(24,2-41,9)
b330	Fluency and rhythm of speech functions	13	68.42%	(47,5-89,3)	7	58.33%	(30,4-86,2)	20	64.52%	(47,7-81,4)	42	53.85%	(42,8-64,9)	62	56.88%	(47,6-66,2)
b455	Exercise tolerance functions	3	15.79%	(0,16-32,2)	1	8.33%	(0 -24)	4	12.90%	(1,1-24,7)	15	19.23%	(10,5-28)	19	17.43%	(10,3-24,6)
b530	Weight maintenance functions	7	36.84%	(15,1-58,5)	0	0.00%	(0-0)	7	22.58%	(7,9-37,3	5	6.41%	(1-11,8)	12	11.01%	(5,1-16,9)
b765	Involuntary movement functions	8	42.11%	(19,9-64,3)	0	0.00%	(0-0)	8	25.81%	(10,4-41,2)	9	11.54%	(4,4-18,6)	17	15.60%	(8,8-22,4)
Activities and Participation																
d230	Carrying out daily routine	4	21.05%	(2,7-39,4)	5	41.67%	(13,8-69,6)	9	29.03%	(13,1-45)	15	19.23%	(10,5-28)	24	22.02%	(14,2-29,8)
d240	Handling stress and other psychological demands	3	15.79%	(0,6-32,2)	3	25.00%	(0,5-49,5)	6	19.35%	(5,4-33,3)	20	25.64%	(15,9-35,3)	26	23.85%	(15,8-31,9)
d350	Conversation	11	57.89%	(35,7- 80,1)	7	58.33%	(30,4-86,2)	18	58.06%	(40,7-75,4)	32	41.03%	(30,1-51,9)	50	45.87%	(36,5-55,2)
d410	Changing basic body position	3	15.79%	(0,6-32,2)	2	16.67%	(0 -37,8)	5	16.13%	(3,2-29,1)	7	8.97%	(2,6-15,3)	12	11.01%	(5,1-16,9)
d430	Lifting and carrying objects	3	15.79%	(0,6-32,2)	2	16.67%	(0 -37,8)	5	16.13%	(3,2-29,1)	7	8.97%	(2,6-15,3)	12	11.01%	(5,1-16,9)
d450	Walking	3	15.79%	(0,6-32,2)	2	16.67%	(0 -37,8)	5	16.13%	(3,2-29,1)	7	8.97%	(2,6-15,3)	12	11.01%	(5,1-16,9)
d455	Moving around	4	21.05%	(2,7-39,4)	2	16.67%	(0 -37,8)	6	19.35%	(5,4-33,3)	9	11.54%	(4,4-18,6)	15	13.76%	(7,3-20,2)
d510	Washing oneself	7	36.84%	(15,1-58,5)	2	16.67%	(0 -37,8)	9	29.03%	(13,1-45)	32	41.03%	(30,1-51,9)	41	37.61%	(28,5-46,7)
d540	Dressing	7	36.84%	(15,1-58,5)	2	16.67%	(0 -37,8)	10	32.26%	(15,8-48,7)	30	39.74%	(28,9-50,6)	41	37.61%	(28,5-46,7)

d570	Looking after one's health	1	5.26%	(0-15,3)	2	16.67%	(0 -37,8)	3	9.68%	(0 -20,1)	13	16.67%	(8,4-24,9)	16	14.68%	(8-21,3)
d640	Doing housework	3	15.79%	(0,6-32,2)	2	16.67%	(0 -37,8)	5	16.13%	(3,2-29,1)	14	17.95%	(9,9-26,5)	19	17.43%	(10,3-24,6)
d750	Informal social relationships	3	15.79%	(0,6-32,2)	2	16.67%	(0 -37,8)	5	16.13%	(3,2-29,1)	14	17.95%	(9,9-26,5)	19	17.43%	(10,3-24,6)
d760	Family relationships	3	15.79%	(0,6-32,2)	3	25.00%	(0,5-49,5)	6	19.35%	(5,4-33,3)	17	21.79%	(12,6-31,0)	23	21.10%	(13,4-28,8)
d770	Intimate relationships	4	21.05%	(2,7-39,4)	8	66.67%	(40-93,3)	12	38.71%	(21,6-55,9)	15	19.23%	(10,5-28)	27	24.77%	(16,7-31,9)
d845	Acquiring, keeping and terminating a job	5	26.32%	(6,5-46,1)	6	50.00%	(21,7-78,3)	11	35.48%	(18,6-52,3)	20	25.64%	(15,9-35,3)	31	28.44%	(20-36,9)
d850	Remunerative employment	5	26.32%	(6,5-46,1)	5	41.67%	(13,8-69,6)	10	32.26%	(15,8-48,7)	24	30.77%	(20,5-41,0)	34	31.19%	(22,5-39,9)
d920	Recreation and leisure	5	26.32%	(6,5-46,1)	2	16.67%	(0 -37,8)	7	22.58%	(7,9-37,3)	21	26.92%	(17,1-36,8)	28	25.69%	(17,5-33,9)
Environmental Factors																
e110	Products or substances for personal consumption	15	78.95%	(60,6-97,3)	10	83.33%	(62,2-104,4)	25	80.65%	(66,7-94,6)	49	62.82%	(52,1-73,5)	74	67.89%	(59,1-76,7)
e165	Assets	0	0.00%	(0-0)	0	0.00%	(0-0)	0	0.00%	(0-0)	11	14.10%	(6,4-21,8)	11	10.09%	(4,4-15,7)
e250	Sound	3	15.79%	(0,6-32,2)	6	50.00%	(21,7-78,3)	9	29.03%	(13,1-45)	5	6.41%	(1-11,8)	14	12.84%	(6,6-19,1)
e310	Immediate family	0	0.00%	(0-0)	4	33.33%	(6,7-60)	4	12.90%	(1,1-24,7)	7	8.97%	(2,6-15,3)	11	10.09%	(4,4-15,7)
e355	Health professionals	3	15.79%	(0,6-32,2)	10	83.33%	(62,2-104,4)	13	41.94%	(24,6-59,3)	11	14.10%	(6,4-21,8)	24	22.02%	(14,2-29,8)
e570	Social security services, systems and policies	2	10.53%	(0-24,3)	2	16.67%	(0 -37,8)	4	12.90%	(1,1-24,7)	7	8.97%	(2,6-15,3)	11	10.09%	(4,4-15,7)
e580	Health services, systems and policies	16	84.21%	(67,8-100,6)	11	91.67%	(76,0-107,3)	27	87.10%	(75,3-98,9)	47	60.26%	(49,4-71,1)	74	67.89%	(59,1-76,7)

There were significant differences in three ICF categories when comparing the frequency with which they had been addressed in purely pharmacological studies and studies with combined interventions. Category b140, "attention functions" has a higher frequency of appearance in pure pharmacological studies, while d770, "intimate relationships"; and e355, "health professionals" are addressed more frequently in combined studies.

b) Qualitative Study

Saturation point was reached after interview number 15 was conducted. Regarding diagnosis, 11 participants were diagnosed with bipolar disorder type 1 and the remaining 4 had a diagnosis of bipolar disorder type 2. From the 15 individuals interviewed 8 (53%) are male and 7 (47%) female. Age of the participants ranged from 24 to 77 years and years of formal study from 1 to 17. Demographic data on the participants are showed in Table 6.

Table 6: Socio-demographic data on the participants. (Freq: frequencies; %: percent; Min: minimum; Max: maximum; M: medium; SD: standard deviation)

		Freq	%	Min.	Max.	M (SD)
Gender	Male	8	53,3			
	Female	7	46,7			
marital status	Single	5	33,3			
	Married	4	26,7			
	Divorced	6	40			
living status	living alone	4	26,7			
	living with parent(s)	4	26,7			
	living with spouse/life partner	5	33,3			
	living with flatmates	1	6,7			
	living in a health/social residence	1	6,7			
working status	working as an employee	6	40			
	independent worker	2	13,3			
	retirement after completing working years/age by law	1	6,7			
	Unemployment	3	20			
	housewife / houseman	1	6,7			
	anticipated retirement due to incapacity	1	6,7			
	Studying	1	6,7			
	Age			24	77	46,93 (14,04)
	years of formal education			1	17	11,87 (4,76)

Both the rating of the impact of BD in daily living as the rating of general health ranged from 1 to 10, with a mode of 4 and 5, respectively.

A total of 372 concepts were extracted from the answers given by the participants. After linking these to the ICF and excluding duplicate concepts within the same protocol 260 codes were obtained, from this 248 correspond to ICF categories. 10 concepts were considered not covered by the ICF, 1 concept was linked to ICF chapters although no second, third or fourth level ICF category seemed accurate enough to allow linking and 1 concept was linked to the component "Personal Factors". From the 248 assignable concepts 101 (41%) were linked to the component 'Body Functions', 4 (2%) to 'Body Structures', 73 (29 %) to the 'Activities and Participation' and 70 (28%) to the 'Environmental Factors" chapter.

In total, the concepts were linked to 88 different second-level ICF categories, also including the more specific third-, and fourth- level categories. Most frequently measured 'body functions' were b126 'temperament and personality functions' (73%), followed by b152 'emotional functions' (67%), and b130 'energy and drive functions' (67%). Within the ICF component 'activities and participation' the categories d920 'recreation and leisure' (47%) and d770 'intimate relationships' (40%), showed the highest relative frequencies. The category e310 'immediate family' (87%) had the highest frequency of appearance within the environmental factors chapter, followed by the category e315 'extended family' (66%). Regarding body structures, no category appeared in more than one protocol. The categories that appeared were s110 'structure of the brain', s540 'structure of the intestine', s630 'structure of reproductive system' and 's710 'structure of head and neck region'. Table 7 shows the relative frequencies of the ICF categories linked to the concepts contained in the interview protocols. Results shown are summarized at the second-level of the classification.

Table 7: Relative frequency of the ICF categories linked to the concepts contained in the interview protocols

ICF Code	*ICF category*	*Frequency*	*Percent*
e310	Immediate family	13	87%
b126	Temperament and personality functions	11	73%
b130	Energy and drive functions	10	67%
b152	Emotional functions	10	67%
e315	Extended family	9	60%
b144	Memory functions	8	53%
b160	Thought functions	8	53%
b134	Sleep functions	7	47%
d920	Recreation and leisure	7	47%
e110	Products or substances for personal consumption	7	47%
d770	Intimate relationships	6	40%
e460	Societal attitudes	6	40%
e580	Health services, systems and policies	6	40%
b140	Attention functions	5	33%
d460	Moving around in different locations	5	33%
b530	Weight maintenance functions	4	27%
d510	Washing oneself	4	27%
d710	Basic interpersonal interactions	4	27%
e320	Friends	4	27%
e355	Health professionals	4	27%
b110	Consciousness functions	3	20%
b117	Intellectual functions	3	20%
b515	Digestive functions	3	20%
b765	Involuntary movement functions	3	20%
d230	Carrying out daily routine	3	20%
d240	Handling stress and other psychological demands	3	20%
d520	Caring for body parts	3	20%
d540	Dressing	3	20%
d640	Doing housework	3	20%
d820	School education	3	20%
d845	Acquiring, keeping and terminating a job	3	20%
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours and community members	3	20%
b156	Perceptual functions	2	13%
b164	Higher-level cognitive functions	2	13%
b280	Sensation of pain	2	13%
b340	Alternative vocalization functions	2	13%
b510	Ingestion functions	2	13%
b525	Defecation functions	2	13%
b640	Sexual functions	2	13%
b810	Protective functions of the skin	2	13%
d166	Reading	2	13%
d360	Using communication devices and techniques	2	13%
d570	Looking after one's health	2	13%
d850	Remunerative employment	2	13%
e125	Products and technology for communication	2	13%
e215	Population	2	13%
e325	Acquaintances, peers, colleagues, neighbours and community members	2	13%
e410	Individual attitudes of immediate family members	2	13%

e415	Individual attitudes of extended family members	2	13%
e465	Social norms, practices and ideologies	2	13%
b167	Mental functions of language	1	7%
b180	Experience of self and time functions	1	7%
b210	Seeing functions	1	7%
b240	Sensations associated with hearing and vestibular function	1	7%
b265	Touch function	1	7%
b410	Heart functions	1	7%
b420	Blood pressure functions	1	7%
b440	Respiration functions	1	7%
b535	Sensations associated with the digestive system	1	7%
b840	Sensation related to the skin	1	7%
d163	Thinking	1	7%
d177	Making decisions	1	7%
d210	Undertaking a single task	1	7%
d350	Conversation	1	7%
d410	Changing basic body position	1	7%
d445	Hand and arm use	1	7%
d470	Using transportation	1	7%
d550	Eating	1	7%
d610	Acquiring a place to live	1	7%
d620	Acquisition of goods and services	1	7%
d720	Complex interpersonal interactions	1	7%
d730	Relating with strangers	1	7%
d740	Formal relationships	1	7%
d750	Informal social relationships	1	7%
d760	Family relationships	1	7%
d830	Higher education	1	7%
d870	Economic self-sufficiency	1	7%
d930	Religion and spirituality	1	7%
e165	Assets	1	7%
e210	Physical geography	1	7%
e225	Climate	1	7%
e420	Individual attitudes of friends	1	7%
e450	Individual attitudes of health professionals	1	7%
e550	Legal services, systems and policies	1	7%
s110	Structure of brain	1	7%
s540	Structure of intestine	1	7%
s630	Structure of reproductive system	1	7%
s710	Structure of head and neck region	1	7%

c) Expert Survey

A total of 68 participants from the 6 WHO World Regions filled in the online questionnaire. The "Americas" and the "European Regions" were mostly represented, with 27b and 22 Experts involved, respectively. Table 8 shows the distribution of the participants in the WHO Word regions.

Table 8: Number of Participants by WHO's world regions

WHO Word Region	Number of Participants
African Region	3
Americas	27
South-East Asia Region	4
Eastern Mediterranean Region	3
West Pacific Region	9
Total	*68*

Regarding the professional background of the participants, 84% were Psychiatrists and only one participant (1,5%) had a background in nursering. Figure 11 shows the distribution of the participants by professional background.

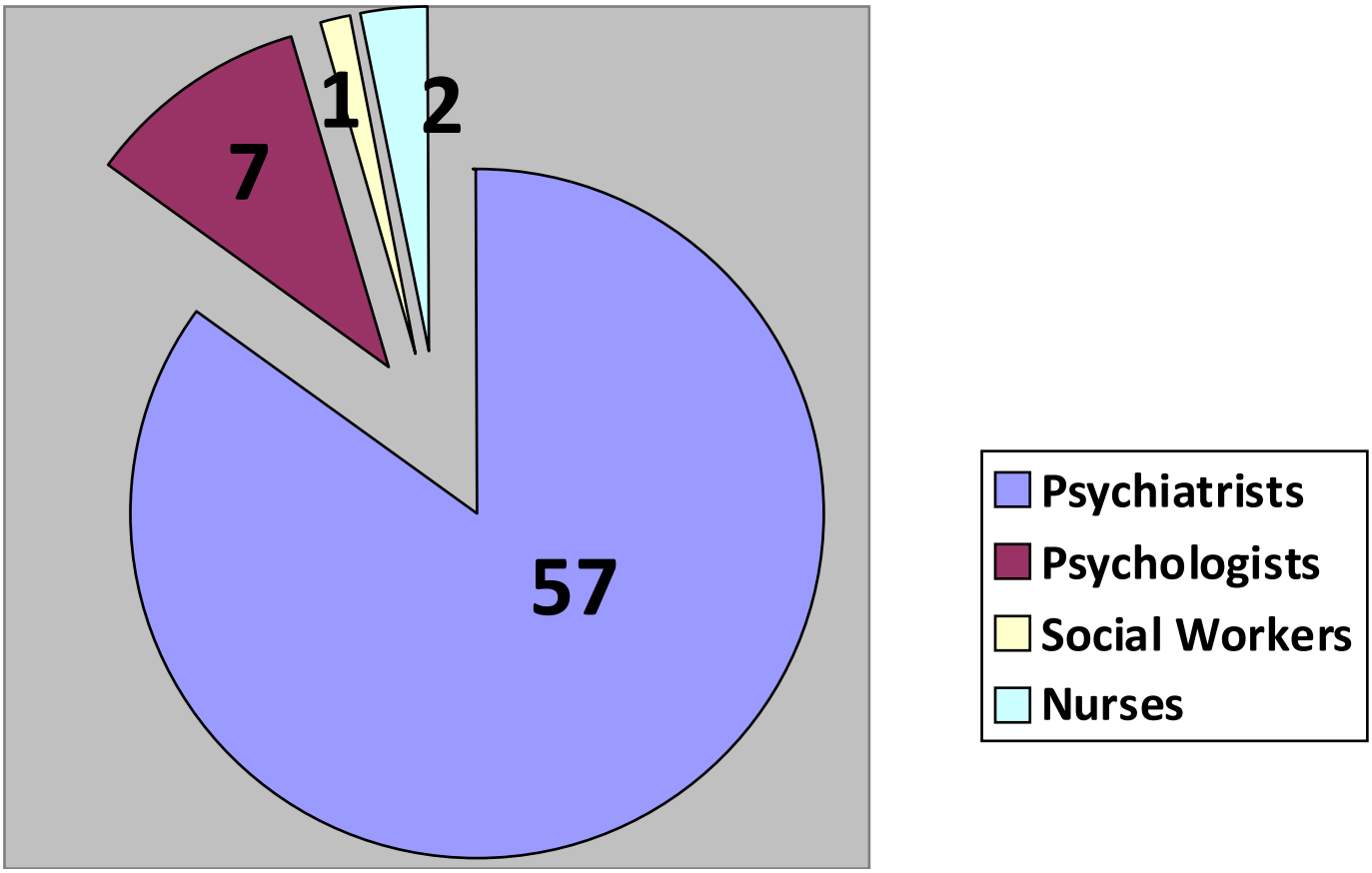


Figure 11: Distribution of participants by professional background

Regarding gender, 19% of the participants were female.

From the 68 answers to the survey, a total of 2065 statements were obtained. After linking those to the ICF a total of 107 ICF 2nd level Categories were obtained at the second level of the classification. Considering also the more specific third-, and fourth- level categories, a total of 130 ICF categories were included. If the answers of one expert were linked more than once to the same category, this category was only considered once. Table 7 shows the relative frequency of the ICF categories linked to the answers obtained in the study at the second level of the classification. From the 130 categories, 42 belong to the "Activities and Participation" domain, 33 categories are "Body Functions", 32 are "Environmental Factors" and 21 are "Body Structures". In total 38 categories reached a frequency of at least 10% of answers. From these, 14 categories are Environmental Factors, 11 are in the "Activities and Participation" domain, 11 are "Body Functions" and 2 are "Body Structures",

The categories with the highest frequency of appearance were e310 "Immediate Family" and e580 "Health Services, Systems and Policies", (75% each), followed by e315 "Extended Family" (72%) and b152 "Emotional Functions" (68%). From the "Body Structures" domain, the category that was considered the most was s580 "Structure of the Endocrine Glands". Regarding "Activities and Participation", d845 "Acquiring, Keeping and Terminating a Job" was the most selected category.

Table 9: Relative frequency of the ICF categories linked to the concepts contained in the answers of the Experts in Bipolar Disorders.

ICF Code	*ICF Category*	*Frequency*	*(%) N=68*
e310	Immediate family	51	75
e580	Health services, systems and policies	51	75
e315	Extended family	49	72
b152	Emotional functions	46	68
s110	Structure of brain	45	66
b130	Energy and drive functions	44	65
d845	Acquiring, keeping and terminating a job	44	65
b134	Sleep functions	41	60
b164	Higher-level cognitive functions	40	59
d570	Looking after one's health	40	59
e110	Products or substances for personal consumption	37	54
d230	Carrying out daily routine	33	49
e460	Societal attitudes	29	43
b140	Attention functions	25	37
e355	Health professionals	24	35
b126	Temperament and personality functions	23	34
b640	Sexual functions	22	32
d760	Family relationships	22	32
d870	Economic self-sufficiency	20	29
e165	Assets	20	29
b160	Thought functions	19	28
b530	Weight maintenance functions	17	25
d850	Remunerative employment	17	25
e570	Social security services, systems and policies	17	25
d240	Handling stress and other psychological demands	15	22
d770	Intimate relationships	15	22
d920	Recreation and leisure	15	22
e320	Friends	14	21
b147	Psychomotor functions	13	19
d910	Community life	13	19
e325	Acquaintances, peers, colleagues, neighbours and community members	12	18
e555	Associations and organizational services, systems and policies	12	18
b144	Memory functions	10	15
s580	Structure of endocrine glands	9	13
d740	Formal relationships	9	13
e410	Individual attitudes of immediate family members	9	13
e415	Individual attitudes of extended family members	9	13
e330	People in positions of authority	7	10
b156	Perceptual functions	6	9

b280	Sensation of pain	6	9
b540	General metabolic functions	6	9
d177	Making decisions	6	9
d710	Basic interpersonal interactions	6	9
d720	Complex interpersonal interactions	6	9
d820	School education	6	9
s410	Structure of cardiovascular system	5	7
e590	Labour and employment services, systems and policies	5	7
b167	Mental functions of language	4	6
b455	Exercise tolerance functions	4	6
b765	Involuntary movement functions	4	6
d950	Political life and citizenship	4	6
e425	Individual attitudes of acquaintances, peers, colleagues, neighbours and community members	4	6
b117	Intellectual functions	3	4
b122	Global psychosocial functions	3	4
b555	Endocrine gland functions	3	4
d175	Solving problems	3	4
d210	Undertaking a single task	3	4
d610	Acquiring a place to live	3	4
d640	Doing housework	3	4
d660	Assisting others	3	4
d750	Informal social relationships	3	4
d930	Religion and spirituality	3	4
e420	Individual attitudes of friends	3	4
b110	Consciousness functions	2	3
b114	Orientation functions	2	3
b180	Experience of self and time functions	2	3
b435	Immunological system functions	2	3
b510	Ingestion functions	2	3
b660	Procreation functions	2	3
b735	Muscle tone functions	2	3
s140	Structure of sympathetic nervous system	2	3
s150	Structure of parasympathetic nervous system	2	3
s420	Structure of immune system	2	3
s560	Structure of liver	2	3
s610	Structure of urinary system	2	3
s710	Structure of head and neck region	2	3
s750	Structure of lower extremity	2	3
d163	Thinking	2	3
d550	Eating	2	3
e240	Light	2	3
e335	People in subordinate positions	2	3
e525	Housing services, systems and policies	2	3
e585	Education and training services, systems and policies	2	3
b235	Vestibular functions	1	1
b330	Fluency and rhythm of speech functions	1	1

b525	Defecation functions	1	1
b545	Water, mineral and electrolyte balance functions	1	1
b610	Urinary excretory functions	1	1
b670	Sensations associated with genital and reproductive functions	1	1
b760	Control of voluntary movement functions	1	1
s210	Structure of eye socket	1	1
s220	Structure of eyeball	1	1
s320	Structure of mouth	1	1
s530	Structure of stomach	1	1
s540	Structure of intestine	1	1
s630	Structure of reproductive system	1	1
s730	Structure of upper extremity	1	1
s760	Structure of trunk	1	1
s770	Additional musculoskeletal structures related to movement	1	1
s810	Structure of areas of skin	1	1
s840	Structure of hair	1	1
d110	Watching	1	1
d115	Listening	1	1
d155	Acquiring skills	1	1
d160	Focusing attention	1	1
d166	Reading	1	1
d220	Undertaking multiple tasks	1	1
d310	Communicating with - receiving - spoken messages	1	1
d355	Discussion	1	1
d450	Walking	1	1
d510	Washing oneself	1	1
d540	Dressing	1	1
d620	Acquisition of goods and services	1	1
d825	Vocational training	1	1
d830	Higher education	1	1
d855	Non-remunerative employment	1	1
d860	Basic economic transactions	1	1
d940	Human rights	1	1
e130	Products and technology for education	1	1
e215	Population	1	1
e225	Climate	1	1
e250	Sound	1	1
e340	Personal care providers and personal assistants	1	1
e360	Other professionals	1	1
e430	Individual attitudes of people in positions of authority	1	1
e440	Individual attitudes of personal care providers and personal assistants	1	1
e445	Individual attitudes of strangers	1	1
e465	Social norms, practices and ideologies	1	1
e535	Communication services, systems and policies	1	1
e560	Media services, systems and policies	1	1

d) ICF Core Sets International Consensus Conference

The ICF Consensus Consensus Conference took place in Madrid from May, 13th (Thursday) until May, 15th (Saturday). 21 participants attended the meeting. 7 were from Spain, 7 from other european countries and 7 from overseas. Table 10 shows the ICF categories included in the comprehensive ICF Core Set for BD. In total, 38 categories were selected. Only one third level category was included, all others categories belong to the second level of the classification. Table 11 shows the ICF categories included in the Brief Core Set for BD. A total of 19 categories was included in the Brief Core Set for BD. Only one ICF third level category was included. No fourth level categories were included either in the comprehensive or in the brief core set for BD.

Comprehensive ICF Core Set

The 38 categories of the Comprehensive ICF Core Set are made up of 14 categories from the component body functions, 14 from the component "Activities and Participation", and 10 from the component "Environmental Factors. No category from the component "Body Structures" was selected. The only category at third level of the classification that was selected belongs to the "Environmental Factors" domain. Most of the body-functions categories belong to chapter 1 "Mental functions" (10 categories). Chapter 2 "Sensory Functions and Pain", chapter 3 "Voice and Speed functions", chapter 5 "Functions of the Digestive, Metabolic and Endocrine systems" and chapter 6 "Genitourinary and Reproductive Functions" are represented by one category each.

Regarding the "Activities and Participation" domain chapter 1 "Learning and Applying Knowledge" (2 categories), 2 ""General Tasks and Demands" (4

categories), 5 "Self-care" (1 category), 7 "Interpersonal Interactions and Relationships" (4 categories), 8 "Major Areas of Life" (2 categories) and 9 "Community, Social and Civil Life" (1 category) are represented in the Comprehensive Core Set.

Most of the ICF categories selected within the "Environmental Factors" domain belong to chapter 4 "Attitudes" (4 categories). Three categories belong to chapter 3 "Support and Relationships" and two categories to chapter 5 "Services, Systems and Policies". Chapter 1 "Products and Technology" is represented by one category. One category, e1101 "Drugs" is at the third level of the classification while all others are at the second level.

Table 10: Categories included in the Comprehensive ICF Core Set for BD

ICF Code	ICF Category Title
Body Functions (14)	
b126	Temperament and personality functions
b130	Energy and drive functions
b134	Sleep functions
b140	Attention functions
b144	Memory functions
b147	Psychomotor functions
b152	Emotional functions
b156	Perceptual functions
b160	Thought functions
b164	Higher-level cognitive functions
b280	Sensation of pain
b330	Fluency and rhythm of speech functions
b530	Weight maintenance functions
b640	Sexual functions
Activities & Participation (14)	
d175	Solving problems
d177	Making decisions
d210	Undertaking a single task
d220	Undertaking multiple tasks
d230	Carrying out daily routine
d240	Handling stress and other psychological demands
d570	Looking after one's health
d710	Basic interpersonal interactions
d720	Complex interpersonal interactions
d760	Family relationships
d770	Intimate relationships
d845	Acquiring, keeping and terminating a job
d870	Economic self-sufficiency
d920	Recreation and leisure
Environmental Factors (10)	
e1101	Drugs
e310	Immediate family
e320	Friends
e355	Health professionals
e410	Individual attitudes of immediate family members
e420	Individual attitudes of friends
e450	Individual attitudes of health professionals
e460	Societal attitudes
e570	Social security services, systems and policies
e580	Health services, systems and policies
	Total: 38 categories

Brief ICF Core Set

From the categories at the second level contained in the Comprehensive ICF Core Set, the following numbers of ICF categories were included in the Brief ICF Core Set: 7 categories from the component "Body Functions", 7 from "Activities and Participation", and 5 from Environmental factors. The only category at third level of the classification that was selected belongs to the "Environmental Factors" domain.

All body-functions categories belong to chapter 1 "Mental functions". Regarding the "Activities and Participation" domain two categories from chapter 2 ""General Tasks and Demands" and two categories from chapter 7 "Interpersonal Interactions and Relationships", are included. Chapter 1 "Learning and Applying Knowledge", 5 "Self-care" and 8 "Major Areas of Life" are represented in the Brief Core Set with one category each.

With respect to the "Environmental Factors" domain, two categories belong to chapter 3 "Support and Relationships" and two to chapter 4 "Attitudes". One category from chapter 1 "Products and Technology" is included at the third level of the classification. All other categories of the Brief Core Set are represented at the second level of the classification.

Table 11: ICF categories included in the Brief Core Set for BD

ICF Code	ICF Category Title
Body Functions (7)	
b126	Temperament and personality functions
b130	Energy and drive functions
b134	Sleep functions
b140	Attention functions
b144	Memory functions
b152	Emotional functions
b160	Thought functions
Activities & Participation (7)	
d175	Solving problems
d230	Carrying out daily routine
d240	Handling stress and other psychological demands
d570	Looking after one's health
d760	Family relationships
d770	Intimate relationships
d845	Acquiring, keeping and terminating a job
Environmental Factors (5)	
e1101	Drugs
e320	Friends
e355	Health professionals
e410	Individual attitudes of immediate family members
e460	Societal attitudes
	Total: 19 categories

Discussion

Discussion by study

a) Systematic Literature Review

El uso de la CIF ha facilitado la identificación y cuantificación de los temas comúnmente tratados en los estudios centrados en el trastorno bipolar. En este sentido, consideramos la CIF útil no sólo como un marco conceptual para el funcionamiento de la discapacidad y la salud, sino también para permitir la comparación de los datos obtenidos en diferentes ámbitos, tipos de estudios y poblaciones, utilizando diferentes metodologías y en base a una variedad de perspectivas. Sin embargo, no fue posible enlazar algunos conceptos a categorías de la CIF. En la mayoría de los casos, creemos que esto se debió a una falta de especificación conceptual en los artículos, pero en algunos casos, los investigadores sintieron la necesidad de códigos de la CIF adicionales para captar la pura experiencia de vivir con un trastorno de salud mental. Por ejemplo, el suicidio fue un tema importante en un gran número de estudios, no sólo como variable dependiente, sino también recogido como dato clínico en la entrada del estudio. Este hecho se convierte en una cuestión a tener muy en cuenta para los profesionales de la salud que trabajan en la asistencia a los enfermos bipolares. A pesar de que la eventual necesidad de incluir una categoría CIF que aborde el suicidio en las versiones futuras de esta clasificación ha sido anticipada antes por el grupo de investigación responsable del desarrollo de los core sets de la CIF para depresión (Alarcos Cieza et al., 2004), es cuestionable en qué medida esto debe ser así.

La CIF no es una clasificación de comportamientos humanos específicos, sino de la salud y de otros ámbitos relacionados. Por lo tanto, no es el propósito de la CIF dar cabida a todos los comportamientos posibles que sean sintomáticos de los trastornos mentales. Investigadores y médicos deben tener esto en cuenta cuando utilicen esta clasificación.

Un número considerable de conceptos se encontraban relacionados con el dominio de los factores personales de la CIF, sin embargo, no existe una especificación de estos factores en el CIF. Aunque la categorización de los factores personales sea controvertida, creemos que estudios adicionales, especialmente los dirigidos a problemas de salud mental, deben tratar de especificar los subdominios de los factores personales para retener la mayor parte de la información recogida en los estudios.

Las funciones del cuerpo con alta frecuencia de aparición reflejan los aspectos clave del TB - a saber, las funciones emocionales, de personalidad y las funciones cognitivas.

Investigaciones recientes indican que la disfunción cognitiva es central en este trastorno (Goodwin, Martinez-Aran, Glahn, & Vieta, 2008). De hecho, el CI premórbido en individuos con TB es más bajo que el de la población sana (Goldberg & Burdick, 2008). La *manía* y los *estados depresivos* tienen un claro impacto sobre la función cognitiva. En los estados eutímicos, el deterioro de la función ejecutiva es el déficit neurocognitivo más consistentemente referido, incluida la planificación y el control cognitivo (Goldberg & Burdick, 2008).

En el ámbito ICF "Actividades y Participación", las categorías más frecuentemente abordadas (por ejemplo, d350, "conversación", con un 58%) no fueron evaluadas en tantos estudios como las funciones del cuerpo -más

frecuentemente estudiadas (por ejemplo, b126, "funciones del temperamento y la personalidad", con el 84%)-. Esto indica que, aunque el impacto de esta condición en la vida cotidiana es bien reconocida (Depp, Davis, Mittal, Patterson, & Jeste, 2006; Dias, Brissos, Frey, & Kapczinski, 2008; Piccinni et al., 2007), no es evaluado de forma sistemática en todos los estudios. La "Conversación" fue la actividad con mayor frecuencia de aparición, probablemente debido a que suele ser evaluada, ya que sirve como un indicador de las dificultades en las relaciones interpersonales y en los procesos mentales, tales como la concentración. La categoría "productos o sustancias para consumo personal" fue vinculada a los conceptos que figuran en el 68% de los artículos, sobre todo debido a la inclusión de la categoría de tercer nivel "drogas".

De los 31 estudios de intervención elegibles, el 62% se basaban en intervenciones farmacológicas y el 39% en tratamientos combinados, incluyendo terapia farmacológica y psicoterapia, psicoeducación y terapia electroconvulsiva. Teniendo en cuenta que la mayoría de los artículos proviene de países de elevado nivel económico, es muy común que las personas con TB estén bajo tratamiento farmacológico de forma regular después de su diagnóstico. Por lo tanto, no es ninguna novedad el que no fuesen encontrados estudios psicoterapéuticos puros. Además, los estudios centrados en la prevención y en otros aspectos significativos fueron excluidos del presente análisis para asegurar que se utilizara una muestra de estudios sobre los individuos con un diagnóstico de TB bien establecido. Mientras que la categoría de la CIF b140, "funciones de la atención", se abordó de manera significativa en un mayor número de estudios farmacológicos, las categorías d770,

"relaciones íntimas", y e355, "profesionales de la salud", fueron halladas en un numero significativamente mayor de estudios con intervenciones combinadas. Sin embargo, como las comparaciones realizadas fueron de exploración, los resultados deben ser interpretados con cautela y confirmados en estudios posteriores.

A pesar de que algunas de las medidas utilizadas no estaban normalizadas, la mayoría de los estudios incluía algún tipo de evaluación sintomática o funcional. Los tres instrumentos más utilizados fueron la "Escala de Hamilton para Depresión" (Hamilton, 1960) con la que normalmente se evalúa la severidad de los síntomas depresivos, la "Young Mania Rating Scale" (Young, et al., 1978), y el GAF (American Psychiatry Association, 1994b), que evalúa el funcionamiento global de acuerdo a los criterios del DSM. Los tres instrumentos son escalas de evaluación. Otros instrumentos centrados en áreas específicas de funcionamiento y discapacidad se utilizaron con menos frecuencia. Este es un dato muy importante dado que los resultados más relevantes del tratamiento del TB son los que referidos a las actividades y ámbitos de participación. Por otra parte, estos son, en definitiva, los resultados más importantes de los servicios de salud y los objetivos que quedan explícitos de la mayoría de la política y legislación relacionada con la discapacidad de personas con problemas de salud (Gannon, 2007).

El mismo resultado refleja también la conocida falta de medidas especificas del estado de salud y calidad de vida para TB (Sanchez-Moreno et al., 2009; Vieta, et al., 2007) y la necesidad de determinar un conjunto estandarizado de áreas de funcionamiento y discapacidad que se encuentran comúnmente afectados en el TB, y que pueda ser utilizado como una base para el desarrollo

de futuros instrumentos. Esa es también una razón de peso para el desarrollo de los core sets de la CIF. El core set de la CIF se definió en una conferencia de consenso que integró los resultados de diferentes estudios preparatorios, a saber:

a) la presente revisión sistemática de la literatura,
b) un estudio cualitativo, con entrevistas individuales con personas con TB, y
c) una encuesta de expertos con profesionales de la salud de todo el mundo diferentes profesiones de la salud.

En este contexto, esta revisión sistemática de la literatura cobra máxima importancia, ya que no sólo reporta de forma sistemática los conceptos contenidos en las variables de resultado de las intervenciones y estudios observacionales en TB, sino que también contribuye al desarrollo del core set para esta condición.

En el momento de la realización de las diferentes etapas de esta revisión, se hizo un esfuerzo en seguir una metodología sistemática predefinida y ser lo más riguroso posible en el análisis cualitativo de los datos. Esta es una de las razones por las que un alto porcentaje de los artículos identificados inicialmente a través de la búsqueda sistemática fueron excluidos.

La búsqueda se limitó a estudios que incluyen solo a participantes mayores de 18 años de edad, dado que no hay un consenso sobre si el TB en los niños es equivalente a adultos en TB (Paykel, 1992). Esta decisión dio lugar a la exclusión de varios artículos presentados como estudios con individuos adultos bipolares, especialmente realizado en los EE.UU., donde las edades legales difieren de la norma europea.

En el presente análisis quisimos excluir otras patologías y contemplar únicamente el TB de tipo I, BD tipo II, trastorno ciclotímico, y TB no especificado como diagnósticos del espectro de BD, siguiendo los criterios de las clasificaciones más comúnmente aceptados, la DSM-IV (American Psychiatry Association, 1994a) y la CIE-10 (World Health Organization, 1996), por esto mismo, los artículos cuya muestra estaba formada por participantes que sufren de otros trastornos aparte de la depresión bipolar (esquizofrenia, por ejemplo), fueron excluidos. Por otra parte, sólo fueron recogidos artículos publicados en inglés. Esta elección se hizo por razones prácticas, y también basada en el hecho de que no contamos con de recursos suficientes para incluir artículos en todos los idiomas. Esta decisión podría haber supuesto una discriminación con respecto a algunos países en los que la comunidad científica no publica en inglés, y es por tanto una de las limitaciones del estudio.

Los términos mesh *maníaco* y *psicosis afectiva** no se incluyeron en la estrategia de búsqueda aplicada en este estudio. La inclusión de estos términos podría haber llevado a la selección de un mayor número de artículos y, potencialmente, a la recuperación de la información adicional.

Por último, sólo se incluyeron los estudios hasta el año 2006. En un área creciente de investigación, tal y como se considera que lo es el TB, sería interesante comparar los resultados de esta revisión con los resultados de otra que incluyese los últimos tres años (2007-2009), así como los términos *maníaco* (mesh) y *psicosis afectiva**. Este sería, sin duda, un importante estudio a realizar en un futuro.

Esta revisión sistemática refleja el enfoque de la investigación en la literatura sobre el TB en los últimos años. La mayoría de los estudios realizados se concentran en las funciones del cuerpo en lugar de actividades y dominios de participación. Los estudios experimentales son, en su mayoría, estudios farmacológicos, lo que refleja la necesidad de estudiar las intervenciones no farmacológicas. Además, nuestro estudio muestra cómo la CIF puede ser útil para identificar y cuantificar la información sobre el funcionamiento de los individuos.

b) Qualitative Study

El uso de la CIF facilitó la identificación y la cuantificación de los problemas relevantes para los pacientes con trastorno bipolar. En este sentido, consideramos que la CIF no sólo es útil como filtro de lectura para el funcionamiento, la discapacidad y la salud, sino también como herramienta de sistematización que permite la comparación de los datos obtenidos en los diversos contextos y a través de diversas metodologías y perspectivas.

El muestreo de participantes incluyó a individuos en diversas etapas de desarrollo, de jóvenes a ancianos, con distintas experiencias profesionales e incluyendo tanto personas que apenas estudiaron como participantes que cursaban una carrera universitaria. Esta heterogeneidad es un aspecto importante del estudio, ya que el impacto de una condición crónica está estrechamente vinculado a las características personales, tales como edad, género y situación socio-cultural.

Con respecto al impacto del TB, se obtuvieron respuestas desde 1 (impacto mínimo o ningún impacto en absoluto) a 10 (impacto completo). Algunos individuos tenían dificultades en contestar a esta pregunta de una manera general, ya que sentían la necesidad de analizar períodos eutimicos y episodios del trastorno por separado. Aunque al final la mayoría de los participantes logró hacer una evaluación general, algunos tendieron a centrarse más en su situación actual, mientras que otros intentaron llegar a un valor que integrase diversos momentos de la vida. Esto puede explicar en parte la gran variabilidad en las respuestas.

Las funciones del cuerpo que aparecieron con una frecuencia más alta reflejan los aspectos clave de los trastornos bipolares, a saber, funciones de la personalidad y temperamento, energía e impulsos y funciones emocionales. Casi la mitad de los participantes mencionó tener dificultades en el área recreativa (d920; el 47%) y también en el establecimiento y el mantenimiento de relaciones íntimas (d770; el 40%). Estas áreas se han identificado antes como afectadas en la gente que sufre de TB. De hecho, diversos estudios concluyeron que estos individuos se involucran en menos actividades de ocio que los controles (Coryell, et al., 1993; Robb, Cooke, Devins, Young, & Joffe, 1997). En la revisión sistemática de la literatura, la "conversación" fue la actividad más frecuentemente encontrada según una selección de estudios de investigación analizados. Estas conclusiones parecen ser congruentes. Como la conversación es un ítem más fácilmente evaluable y las dificultades en mantener una conversación pueden conducir a las dificultades en las relaciones interpersonales, esto último resulta más evidente para los pacientes.

Los factores ambientales con una frecuencia más alta se relacionan con el soporte social percibido por los individuos. De hecho, la mayor parte de los entrevistados ha referido algún tipo de ayuda social, aunque las fuentes variaban, incluyendo la familia cercana y extensa, amigos, relaciones íntimas y profesionales.

La traducción a categorías CIF fue realizada según las reglas de enlace predefinidas (Alarcos Cieza, Szilvia Geyh, Somnath Chatterji, Nenad Kostanjsek, Bedirhan Ustun, et al., 2005) Siempre que el evaluador tuvo dudas sobre la atribución de cierta categoría, se invitó a otro investigador familiarizado con las reglas de enlace a que la realizara también una valoración de la misma. El uso de las reglas de enlace predefinidas ha mostrado previamente que produce un alto acuerdo total entre los evaluadores (91,4% en el segundo nivel de la clasificación) (A. Cieza, et al., 2002a). Sin embargo, el hecho de que la traducción a categorías CIF refleje principalmente la opinión entrenada de un evaluador puede contribuir a provocar un sesgo y es por lo tanto una limitación del análisis de datos.

Por razones de comodidad, este estudio fue desarrollado sólamente en una institución de salud, perteneciente al área de salud II de la Comunidad Autónoma de Madrid, lo cual puede constituir otra limitación puesto que los datos recogidos pueden reproducir principalmente la opinión de una muestra madrileña urbana de pacientes. Puesto que el impacto de los factores ambientales es una de las variables en estudio, una muestra más grande que incluyera a pacientes que vivan en ciudades más pequeñas, inmigrantes y pacientes que asistan a servicios médicos privados, entre otros, sería necesaria para que se viera reflejada en los resultados la heterogeneidad de la

población española. Los efectos de esta limitación son minimizados por el hecho de que esta área de Madrid incluye a gente de diversos ambientes y características socio-económicas, y que se hizo un esfuerzo para reclutar pacientes con diferentes características sociodemográficas.

Este estudio ayuda a superar la falta de investigación cualitativa en el área del trastorno bipolar y el funcionamiento y la calidad de vida, una carencia que ya ha sido señalada con anterioridad (Michalak, Yatham, Kolesar, & Lam, 2006). Además, en la mayor parte de los estudios en los que los datos fueron recogidos mediante entrevistas u otros métodos cualitativos no se hizo ningún análisis estadístico, lo que conduce a dificultades en la comparación de estudios y en la generalización de resultados. En resumen, consideramos que el uso de entrevistas semi-estructuradas permitió que diéramos voz a los pacientes, sin obligación de ajustarse a categorías predefinidas, y el uso de la CIF sirvió como una herramienta adecuada para identificar y cuantificar la información sobre el funcionamiento de los pacientes, así como para superar algunas de las dificultades con que se enfrentan los investigadores a la hora llevar a cabo una investigación cualitativa.

c) Expert Survey

La metodología utilizada permitió la recogida de datos proveniente procedentes de diferentes países, contribuyendo así a superar la limitación que supone la dificultad de generalización de los resultados obtenidos a diferentes países que es frecuentemente apuntada en distintas investigaciones y en particular en los estudios que hacen uso de técnicas cualitativas. Más aún, la utilización de la CIF posibilitó que incluso aspectos culturalmente marcados

fuesen cuantificados y analizados. El hecho de haberse logrado la participación de todas las regiones mundiales de la OMS era uno de los objetivos a que nos propusimos. Por escasez de recursos y motivos de conveniencia no fue posible incluir participantes de diferentes países en el estudio cualitativo con pacientes y creemos poder superar así en parte esa limitación y crear instrumentos que, tal como el modelo en que se basan, sean adecuados y válidos a nivel mundial.

Por otra parte, la gran mayoría de los participantes es médico especialista en Psiquiatría, siendo el número de enfermeros y asistentes sociales bastante reducido. Esta es una limitación del estudio que probablemente tenga que ver con dos factores: En primer lugar los criterios de elegibilidad aplicados a los posibles participantes, que pretendíamos que tuviesen experiencia profesional directa y específica de al menos cinco años en el tratamiento, cuidado o educación de individuos con TB, siendo difícil encontrar, en particular en países de bajos recursos, profesionales de estas áreas específicamente dedicados al TB. Por otra parte, y al haber sido este un estudio coordinado por el Departamento de Psiquiatría de la Universidad Autónoma de Madrid, el acceso a profesionales de esa área resultó más fácil.

Considerando las categorías con una frecuencia superior a 10%, el dominio de la CIF "factores ambientales" fue el más representado en las respuestas de los expertos, con 11 categorías seleccionadas. Es también en este dominio que se sitúan las categorías que obtuvieron mayores frecuencias relativas, lo que parece indicar un reconocimiento de la importancia de estos factores por parte de profesionales de áreas tradicionalmente ligadas a un modelo explicativo de la discapacidad que a lo largo de la historia apenas los consideraba. Por otro lado, esta conclusión refuerza la necesidad de crear instrumentos basados en

modelos biopsicosociales capaces de contribuir a la evaluación e intervención de los contextos, así como dentro de los mismos.

Por otra parte, el dominio de actividades y participación obtuvo también una alta representación y, si tuviésemos en cuenta incluso categorías ligadas una vez, el porcentaje de categorías de este dominio supera el de los factores ambientales. El impacto del TB en la participación es conocido y ha sido documentado previamente. Sin embargo, si algunas actividades tales como mantener un trabajo o cuidar de la propia salud parecen estar típicamente afectadas independientemente de características ambientales y/o personales, la importancia de ciertas actividades depende en gran medida de características personales e incluso culturales. Así, tal vez sea posible decir que el soporte de la familia cercana es casi siempre un factor relevante a considerar, mientras que la calidad del aire solo tendrá implicaciones en algún caso específico, pero es más difícil concluir si la educación superior es más o menos afectada o relevante que la adquisición de bienes y servicios de una forma general para estas personas.

d) ICF Core Sets International Consensus Conference

El proceso de consenso, que integró pruebas[1] de los estudios preliminares y la opinión de los expertos, condujo a la definición de la primera versión de los core sets comprehensivo y breve para el TB.

El mayor desafío fue el de evitar la perspectiva diagnóstica en favor de una perspectiva más amplia capaz de describir toda la experiencia de funcionamiento en individuos con TB. Hubo situaciones en que algunos expertos argumentaban la no inclusión de una categoría por no ser la afectación del área a que se refiere específica al TB o no tratarse de un área de evaluación obligatoria en el diagnóstico del TB. Sin embargo, es importante referir que los propios expertos se preocuparon en incluir aspectos de funcionamiento y alertarse mutuamente para el hecho de que no buscábamos crear un instrumento de evaluación y/o diagnóstico.

Tanto el core set comprehensivo como el core set breve para TB son los más cortos hasta hoy. El tema del tamaño de los listados finales fue mencionado por los propios expertos, considerando algunos que tal vez el número de categorías incluidas no fuese suficientemente grande, mientras que otros insistieron en la necesidad de mantenerlo corto para aumentar 'practicabilidad' del instrumento. Incluso en los debates sobre categorías específicas algunos expertos se dedicaban a defender la "comprehensibilidad", mientras que otros defendían la "practicabilidad". En numerosas ocasiones los expertos procuraron obtener más indicaciones acerca del número de categorías a incluir o el nivel de especificidad deseado. La consigna dada a los

[1] La palabra "pruebas" se utiliza en este contexto como equivalente castellano de la palabra "evidence" en inglés.

participantes fue la de incluir el menor número de categorías posible para mantener el core set corto, y consecuentemente aplicable en la práctica cotidiana, y el número mínimo necesario para cubrir las áreas relevantes[2]. El tema del equilibro entre cantidad mínima y la cantidad necesaria de categorías fue un asunto central en los debates entre los participantes.

Puesto que el TB es un trastorno mental, es natural que un gran número de categorías del dominio "funciones mentales" pertenezca al capítulo de las funciones mentales. Otras funciones corporales, concretamente la "sensación de dolor", "funciones relacionadas con la fluidez y el ritmo del habla", "funciones del mantenimiento de peso" y "funciones sexuales", fueron también incluidas en el core set comprehensivo.

Con respecto al dominio "actividades y participación" fueran incluidas categorías de seis de los nueve capítulos de la CIF: "Aprendizaje y aplicación del conocimiento", "tareas y demandas generales", "autocuidado", "interacciones y relaciones interpersonales", "áreas principales de la vida", "vida comunitaria, social y cívica". Sin embargo, la inclusión de categorías de los restantes capítulos de este dominio fue discutida. En la mayoría de los casos un mismo grupo de trabajo votó a favor de la inclusión de esas categorías, mientras que los otros dos prefirieron no incluirlas para evitar el solapamiento con otras categorías. Una de las categorías que mayor debate ocasionó fue d830 "Educación superior". Algunos expertos querían incluirla por tratarse de un tema de gran importancia en la actualidad. Un experto mencionó incluso la existencia de programas específicos para ayudar los individuos con TB a concluir la educación superior. El argumento de que la educación superior se

[2] En ingles y tal como fue dicho a los expertos:"as few categories as possible and as many as necessary"

aplica a todos los seres humanos pero no es específica al TB ni esencial en la evaluación del funcionamiento condujo a que esta categoría no fuese finalmente incluida. La categoría "Relaciones íntimas" fue incluida tras haberse decidido la inclusión de la categoría "Relaciones familiares" y uno de los expertos haber mencionado que, aunque esta última fuese muy relevante y tuviese gran importancia en el tratamiento, los propios pacientes consideran las relaciones íntimas particularmente primordiales tal y como demuestran los datos.

En el dominio de los "factores ambientales" fueron seleccionadas nueve categorías de segundo nivel y una de tercer nivel. La mayoría de las categorías se refieren al soporte y actitudes de otros. Así, están incluidos la familia cercana, los amigos y los profesionales de la salud. De hecho, individuos que sufren de trastornos mentales siguen siendo víctimas de estigma y discriminación en todas partes del mundo, lo cual influye de manera crucial en su comportamiento, vida social y funcionamiento general y recuperación (World Health Organization, 2001c).

Tras ponderar la inclusión de la familia lejana, los expertos concluyeron que en la mayoría de los casos existe una mayor dependencia y influencia del soporte y de la actitudes de familiares cercanos con respecto al TB, y que la influencia de la familia lejana está más determinada por otros factores (ej. la cultura) que propiamente el TB. Igualmente surgido la cuestión de la inclusión de otros profesionales, pero finalmente los expertos consideraron que los profesionales más relevantes son aquellos que están directamente involucrados en el tratamiento, y que estos se considerarían profesionales de la salud, independientemente de que se trate de médicos o terapeutas ocupacionales.

La posible inclusión de la categoría e325 "clima" fue también debatida, una vez puesto en relieve que incluiría las variaciones estacionales. El experto de Camboya argumentó en contra de su inclusión que estas no tienen ninguna influencia en sus pacientes. Al final el grupo optó por no incluir esta categoría. La definición de e1101 "drogas" de la CIF suscitó algunas dudas entre los expertos, ya que algunos pensaban que se refería al consumo y abuso de sustancias no prescritas. Una vez que esto fue aclarado y que los expertos se pusieron de acuerdo en entender "drogas" como terapia farmacológica, fueron unánimes en que esta categoría debería ser incluida en los core sets para TB. Esta fue la única categoría de tercer nivel seleccionada, una vez hubo acuerdo en considerar que los aspectos relacionados con el tratamiento farmacológico deberían ser objeto de evaluación específica y que las demás categorías contenidas en e110 "productos para el consumo personal" no son tan importantes en el TB como las demás categorías a incluir en los core sets.

Ninguna categoría del dominio "estructuras corporales" fue incluida. Sin embargo, se consideró la inclusión de s110 "estructura del cerebro". De los argumentos a favor de su inclusión destaca el hecho de que muchas veces se realicen electroencefalogramas a individuos que terminan siendo diagnosticados con TB y que la inclusión de una estructura corporal sería importante para reducir el estigma asociado a las enfermedades mentales. Sin embargo, se mencionó que no hay alteraciones en la forma y volumen del cerebro de los individuos con TB y que, aunque a veces existen alteraciones en las funciones, estas no se encuentran asociadas a alteraciones estructurales, tornando la información sobre esta estructura irrelevante.

El proceso de elaboración del core set breve consistió en jerarquizar las categorías incluidas en el core set comprehensivo para seguidamente establecer un punto de corte, por debajo del cual las categorías no serian incluidas. Los principales debates se centraron en torno a jerarquizar dos grupos de categorías: d570 "cuidar de la propia salud", b640 "funciones sexuales" y b530 "funciones relacionadas con el mantenimiento del peso" por una parte y e310 "familia cercana", e320 "amigos" y e355 "profesionales de la salud" por otra. Con relación al primer grupo de categorías, dos expertos consideraban que las categorías "funciones sexuales" y "cuidado de la propia salud" deberían ser colocadas en una posición superior del listado, ya que afectan de forma importante al pronóstico. Otro participante, sin embargo, defendía el valor dado a la categoría "mantenimiento del peso", puesto que los pacientes tienen dificultades en esta área y que el impacto de la medicación en el peso es frecuentemente uno de los motivos por el cual muchos pacientes optan por no tomar la medicación, afectando así el curso de la enfermedad. Finalmente, las categorías "Funciones sexuales" y "Mantenimiento del peso" fueron mantenidas en una posición inferior de las categorías del dominio "Funciones corporales", acabando por ser excluidas, mientras que el "Cuidado de la propia salud" fue colocado en una posición elevada del dominio "Actividades y participación" por considerarse que incluye aspectos ligados al peso y a la sexualidad, entre otros.

Con relación a los "Factores ambientales", un experto consideró que para muchos pacientes los amigos tienen más importancia que los profesionales de la salud. Otro experto recordó que, mientras que en algunas culturas los profesionales de la salud tienen una actitud bastante desestigmatizante, en

otras los pacientes son estigmatizados por los propios profesionales de la salud y que el estigma sigue influyendo los profesionales. Al final, las categorías referidas a la familia, amigos y profesionales de la salud fueron colocadas en posiciones elevadas e incluidas en el core set breve para TB.

El hecho de que la conferencia se celebrara en presencia de expertos de varios países ha contribuido al enriquecimiento de esta reunión y de su producto final: el core set comprehensivo y el core set breve para el trastorno bipolar. Por otra parte, hay que lamentar que estuvieran representadas pocas profesiones (psiquiatras, psicólogos y enfermeros). Existió, no obstante, un esfuerzo de los expertos para intentar considerar qué es lo que sería importante para otros profesionales de salud, así como pensar en culturas diferentes.

Es necesario tener en cuenta que los resultados obtenidos a través de cualquier proceso de consenso pueden diferir de un grupo para otro, por lo que es importante enfatizar la necesidad de validar esta primera versión de los core sets desde la perspectiva de diferentes grupos profesionales y en diferentes países. Es igualmente importante testar esta primera versión desde la perspectiva del individuo con TB y en diferentes contextos clínicos. También es importante señalar que el número de categorías incluidas puede ser alterado en base a los resultados de los estudios validación. Así, hay que subrayar que la utilización de esta primera versión de los core sets está indicada solo para la elaboración de estudios piloto y de validación.

Discussion regarding hypothesis 1

> *The ICF is a content valid classification to address the problems of persons with bipolar disorders from their own perspective"*

Basándonos en el significado original del término (Cronbach & Meehl, 1955), validez de contenido con respecto a la CIF se refiere a la extensión con la cual la información relacionada con la salud está representada de forma adecuada, sin dejar de fuera nada que pudiese ser considerado importante. Un prerrequisito al estudio de la validez de contenido de la CIF en Medicina es, por tanto, la consideración del largo espectro de información referente al funcionamiento y discapacidad relevante en la medicina clínica, así como una metodología estandarizada que permita la traducción de esa información a la CIF.

En el presente trabajo se recogió información relevante de funcionamiento y discapacidad desde la perspectiva de individuos con TB, profesionales de la salud y expertos. La metodología utilizada para traducir esa información a la CIF es referida como "linking" (en inglés) o enlace (en castellano).

La metodología de enlace fue originalmente desarrollada para traducir el Cuestionario de evaluación del estado de salud a la CIF. (A. Cieza, et al., 2002a). Esta metodología fue posteriormente actualizada (Alarcos Cieza, Szilvia Geyh, Somnath Chatterji, Nenad Kostanjsek, Bedirhan Ustun, et al., 2005) y aplicada no sólo a cuestionarios de salud, sino también para enlazar centenares de evaluaciones clínicas (Thomas Brockow, Alarcos Cieza, et al., 2004; T. Brockow et al., 2004; Geyh, et al., 2007; Wolff et al., 2004) y decenas de intervenciones clínicas (Boldt et al., 2005). En el presente estudio, esta

metodología fue empleada para traducir la información recopilada de los individuos con TB, así como de los expertos internacionales en el campo y la contenida en la investigación reciente conducida al respecto de esta enfermedad. La metodología de enlace ("linking") consiste en dos pasos principales. El primero es la identificación de los conceptos contenidos en la información relacionada a la salud para ser luego traducida a la CIF. El segundo paso se refiere a la traducción propiamente dicha de esos conceptos a la CIF.

En el caso de los datos cualitativos, como los obtenidos a través de las entrevistas individuales, los conceptos en las "unidades de significados" son identificados. Una unidad de significado es definida como una unidad específica de texto, ya sea de un par de palabras o de algunas frases, con un tema común (Karlsson, 1995). Una unidad de significado no sigue las normas gramaticales lingüísticas. En su lugar, el texto es divido donde el investigador identifica un cambio en el sentido.

Tras la identificación de los conceptos, éstos son traducidos a la CIF: En la metodología de enlace, diez diferentes reglas de enlace fueron descritas para aplicar en este segundo paso, siendo la más relevante de ellas la obligatoriedad de enlazar los conceptos a la categoría que de forma más precisa os representa.

Considerando tanto los tres estudios preliminares como las categorías de la "checklist" de la CIF que se utilizaron en la evaluación de los 128 pacientes bipolares en estado eutímico, 189 categorías de segundo nivel fueron utilizadas para describir el funcionamiento, la salud y la discapacidad de acuerdo con las perspectivas del investigador, del profesional de la salud, el individuo con TB y

los expertos. En cada uno de los estudios, los parámetros que se referían a las características demográficas y a los eventos de vida fueron enlazados a "factores personales", aun no estando este capítulo todavía definido en la CIF. Adicionalmente, fueron utilizados los indicadores "no cubierto" y "no determinado". El indicador "no cubierto" se refiere a aspectos que se sitúan fuera del ámbito de la CIF, mientras que "no determinado" se refiere a aspectos que sí están cubiertos por la CIF pero que no están suficientemente definidos como para hacer posible el enlace a una categoría específica de la clasificación.

En el caso de las entrevistas individuales, un total de 372 conceptos fueron extraídos de las respuestas dadas por los participantes. Después de traducir estos conceptos a la CIF y excluir conceptos duplicados, se obtuvieron 260 códigos de la CIF. De estos, 248 (95,4%) corresponden a códigos CIF, 1 concepto (0,38%) fue traducido a un capítulo entero de la CIF, 1 concepto fue ligado al apartado "factores personales" (0,38%) y 10 conceptos (3,8%) fueron considerados "no cubiertos" por la CIF. De acuerdo con nuestros resultados, parece haber muy pocos conceptos mencionados por los pacientes que no estén contenidos en la CIF: Estos pueden ser agrupados en tres tipos: 1) conceptos que están relacionados con el ámbito de la CIF, pero no incluidos en el nivel de especificación con que fueron nombrados por el individuo (0,38% de los conceptos), 2) conceptos que están relacionados con el ámbito de la CIF pero no están descritos en la clasificación por tratarse de factores personales (0,38%) y 3) conceptos que se sitúan fuera del ámbito de la CIF (3,8%) , tales como especificaciones "Necesito más tiempo para hacer todo".

Con base en los resultados obtenidos - 95% de los conceptos enlazados a la CIF – la CIF parece poseer los códigos necesarios para describir el funcionamiento y la discapacidad de acuerdo con la perspectiva del individuo con TB. Sin embargo, estudios adicionales con mayor número de participantes y características demográficas, como nacionalidad y país de residencia, distintas son necesarios para soportar la validez de contenido de la CIF desde la perspectiva del paciente.

Discussion regarding hypothesis 2

> *"The ICF Core Sets for BD will share categories with the previously published ICF Core Sets for Depression"*

La primera versión de los Core Sets de la CIF para la depresión fue publicada en el año 2004 por la "ICF Research Branch" en colaboración con otras instituciones en Suiza, Portugal, Holanda y EEUU (Alarcos Cieza, et al., 2004). La metodología utilizada se asemeja a la usada en el presente proyecto, aunque presenta algunas diferencias: los datos preliminares se obtuvieron a través de a) un ejercicio de Delphi, b) una revisión sistemática de la literatura y un estudio empírico con pacientes depresivos. De estos estudios se obtuvo un conjunto de 323 categorías de los diferentes niveles de la clasificación, de los cuales 163 eran funciones corporales, 22 estructuras corporales, 91 pertenecían al dominio "Actividades y Participación" y 47 se refieran a factores ambientales. En total, 121 categorías fueron incluidas en el Core set comprehensivo mientras que la primera versión del Core set breve para depresión engloba un total de 31 categorías.

Tal y como ha sido expuesto a lo largo del presente trabajo, las 128 categorías base que se presentaron a un grupo de expertos se obtuvieron a través de tres estudios preliminares diseñados expresamente para el efecto, a saber, una revisión sistemática de la literatura, un "survey" con expertos en el área del trastorno bipolar (TB) y entrevistas cualitativas realizadas con individuos diagnosticados de TB del tipo I y II: Adicionalmente se presentaron datos empíricos de pacientes bipolares en estado eutímico a quienes fue aplicada la "Checklist" de la CIF (World Health Organization, 2001b) en dos hospitales de distintas Comunidades Autónomas españolas. La primera versión del Core Set comprehensivo para TB contiene un total de 38 categorías, siendo así visiblemente más reducida que la primera versión comprehensiva para depresión. El core set breve para TB contiene 19 categorías.

Comparando ambos core sets comprehensivos, y empezando por las "funciones corporales", se concluye que de las 14 categorías integradas en el core set para TB, solo dos no fueron incluidas en el core set para depresión: b156 "funciones perceptivas" y b330 "fluencia y ritmo del habla". La primera categoría se refiere a un conjunto de dificultades frecuentemente referidas en la literatura acerca del trastorno bipolar y que se encuentran de forma particular en las fases maniacas de dicho trastorno, no formando parte del cuadro clínico del trastorno depresivo unipolar ni manifestándose en las fases depresivas de la afectación bipolar. Así, parece evidente que tenga sentido incluir esta categoría en un listado de aspectos importantes a tener en cuenta en el trabajo con individuos con TB y excluirla de los core sets para depresión.

También la fluencia y el ritmo del habla se ven más afectados en los episodios maníacos, en los que el sujeto presenta normalmente un discurso acelerado y,

a pesar de que el discurso pueda volverse más lento en episodios depresivos, este no es un aspecto central o tan evidente como el contrario.

A pesar de que el core set comprehensivo para depresión contiene 31 categorías más de funciones corporales que el de trastorno bipolar, solo seis categorías de segundo nivel de este dominio representadas en el core set para depresión no fueron tenidas en cuenta en los core sets para TB. Son: b780 "Sensaciones relacionadas con los músculos y las funciones del movimiento", b535 "Sensaciones asociadas con el sistema digestivo", b460 "Sensaciones asociadas con los sistemas cardiovascular y respiratorio", b117 "funciones intelectuales", b147 "funciones psicomotoras" y b180 "Funciones de la experiencia del propio y del tiempo". De estas, b117 "funciones intelectuales" y b180 "Funciones de la experiencia del propio y del tiempo" fueron objeto de debate en la reunión pero no alcanzaron el número de votos necesarios para su inclusión. El argumento más importante que parece haber convencido en gran medida a los participantes para no votar por la inclusión de la categoría b117 fue que, teniendo en consideración la definición de la CIF para esta categoría, así como las funciones que incluye y excluye, las dificultades cognitivas de los individuos con trastorno bipolar parecen ser justo aquellas que son excluidas de la definición.

Las restantes categorías del apartado "funciones corporales" del core set comprehensivo para depresión no incluidas en el core set comprehensivo para TB son categorías de niveles más específicos de la clasificación que se refieren a las categorías de segundo nivel ya contempladas y que, en su mayoría, se encuentran representadas también el core set para TB. El grupo de expertos de TB parece haber preferido la opción de no "bucear" (entendido como 'entrar en

categorías muy específicas') frecuentemente, lo que puede suponerse que tiene que ver con el énfasis colocado en elegir el menor número de categorías necesario en detrimento de la exhaustividad. Este aspecto fue discutido en diversas ocasiones a lo largo de la reunión, una vez que los participantes se preocuparon en establecer un equilibro entre los dos principales criterios de inclusión que se les pidió que considerasen: el menor número de categorías posible para mantener el core set corto y consecuentemente aplicable en la práctica cotidiana y el número mínimo necesario para cubrir las áreas relevantes.

Respecto a las estructuras corporales ninguno de los core sets para trastornos afectivos contiene ninguna categoría de este dominio, ya sea de segundo nivel o de niveles más específicos.

En cuanto a "Actividades y Participación", 14 categorías fueron incluidas en el core set comprehensivo para TB y 48 en el de depresión. La totalidad de las categorías incluidas en el core set para TB fueron también seleccionadas por los expertos en depresión. También en este dominio de la CIF el grupo de expertos involucrado en el desarrollo de los Core Sets para depresión optó por "bucear" en la clasificación e incluir 3 categorías del tercer nivel de la clasificación, mientras que los Core Sets para TB contienen exclusivamente categorías del segundo nivel. De la comparación de ambos Core Sets se concluye que el grupo de depresión ha optado por incluir aspectos de la vida cotidiana cuya afectación, aunque sea bastante frecuente en casos de depresión, no es específica a esta condición de salud ni depende de procesos, funciones o estructuras directamente afectadas por la depresión. Algunos ejemplos serian las categorías que se refieren a "ver", "oír", "utilizar medios de

transporte", "conducir" o "hablar". Todas estas actividades, aunque no estén exclusivamente afectadas en el caso de depresión ni su afectación sea necesaria para el establecimiento del diagnóstico, son actividades que al verse frecuentemente afectadas en individuos con depresión, limitan su participación en la sociedad. Se podría considerar que el grupo de expertos en TB ha optado por incluir los aspectos que *generalmente* se ven afectados por el trastorno, mientras que los Core Sets para depresión incluyen varias áreas que *eventualmente* podrán, de forma no necesariamente acumulativa, verse afectados por la depresión.

También en el dominio de los "factores ambientales" el core set comprehensivo de depresión contiene la totalidad de las 10 categorías que componen los factores ambientales del core set comprehensivo para TB. Ambos core sets contienen una sola categoría de tercer nivel, e1101 "drogas". Una de las diferencias quizás más evidentes entre ambos listados es que el core set para depresión contiene bastantes más categorías de los capítulos e3 e4, referentes al soporte y a las actitudes de otros, respectivamente. Así, ambos grupos consideran el soporte y las actitudes de otros relevantes en los dos trastornos, pero el grupo de expertos en TB optó por incluir sólo la familia cercana, los amigos y los profesionales de salud como fuentes de apoyo y actitudes importantes, mientras que el grupo de depresión ha incluido también a las personas en cargos de autoridad y la familia lejana, entre otros.

En cuanto a los core sets breves para depresión y para TB, estos presentan un número bastante semejante de categorías (19 en el caso del TB y 21 en el core set de depresión). De las 19 categorías elegidas para el TB, 13 de ellas se encuentran también en el core set breve para depresión, aunque en

algunos casos en este ultimo core set se haya optado por incluir formas más especificas de las mismas categorías.

En resumen, es posible afirmar que existe un gran número de categorías comunes en ambos core sets. Considerando las versiones comprehensivas de los cores sets, todas las categorías del core set de TB están incluidas en el core set de depresión, a excepción de las categorías del dominio "funciones corporales". Sin embargo, parece que la dinámica de grupo que se generó en las reuniones condujo a la valoración de aspectos distintos en el proceso de selección de las categorías, contribuyendo así a core sets de extensión bastante distinta. Concretamente, el grupo de expertos en el TB parece haber buscado más la concisión, optando por las categorías que más frecuentemente se ven afectadas, mientras que el grupo de expertos en depresión optó por incluir todas las áreas necesarias para una descripción exhaustiva del impacto de la depresión en el funcionamiento. Más aún, los core sets para TB parecen contener categorías más específicas al TB mientras que los core sets para depresión incluyen más categorías que constituyen áreas afectadas de forma transversal en varias trastornos.

Discussion regarding hypothesis 3 and 5

"The ICF domain that will be mostly represented in the ICF Core Sets for BD will be Activities and Participation"

"The Activities and Participation ICF domain will be higher represented when addressing the Individual Perspective than in the other studies."

La primera hipótesis "El dominio de CIF más representado en los Core Sets para TB será el de actividades y participación" se confirma parcialmente ya que los dominios de "Actividades y participación" y "funciones corporales" se ven representados con el mismo número de categorías, 14 en core set comprehensivo y siete en el core set breve.

Sin embargo, haciendo una comparación del número de categorías obtenido por dominio en cada uno de los estudios preliminares y considerando solo categorías con una frecuencia superior a 10%, vemos que tanto en la revisión sistemática de la literatura como en las entrevistas cualitativas el mayor número de categorías pertenece al dominio de las funciones corporales. La segunda hipótesis "El dominio de actividades y participación obtendrá una mayor representación en el estudio de la perspectiva individual que en los demás" fue por tanto refutada.

En el caso de la encuesta con expertos se obtuvieron más factores ambientales. Así parece que, de acuerdo con la literatura y los propios individuos con trastorno bipolar, son más las funciones corporales afectadas que las actividades que se ven afectadas por el TB. Esto no significa, no obstante, que el grado de afectación en las funciones corporales sea superior al impacto del TB en las actividades. De hecho, del total de 60 categorías del dominio de actividades y participación, 17 de ellas fueron atribuidas en los tres estudios preliminares y el estudio empírico.

Es interesante constatar que, considerando categorías con una frecuencia mínima de 10%, las categorías del apartado "Actividades y participación" corresponden a un 40% de las categorías identificadas en la revisión

sistemática de la literatura, 32% de las categorías identificadas en las entrevistas individuales y 28% de las categorías identificadas en el survey de expertos, y, no obstante, constituyen el 37% de las categorías incluidas en ambos core sets. Esta conclusión parece ir en contra de la idea de sentido común de que los profesionales de la salud se preocupan más por la etiología de las enfermedades que por su impacto en el funcionamiento cotidiano.

Discussion regarding hypothesis 4

> *The Body Structure s110-"Structure of the brain" or a more specific category within the brain structure will be the only Body Structure in the ICF Core Sets for BD*

Ninguna categoría del dominio "Estructuras corporales" fue incluida en ninguna de las dos versiones de los Core Sets para TB, estando por tanto esta hipótesis refutada. En la reunión de consenso la mayoría de los participantes estuvieron de acuerdo desde un principio en no incluir la categoría s110, a pesar de que esta fue la única estructura corporal que no obtuvo unanimidad desde el inicio en su exclusión. El argumento más enfatizado contra su inclusión fue que el TB no está asociado a ninguna alteración cerebral y no es necesario efectuar exámenes del cerebro para diagnosticar o tratar un individuo con trastorno bipolar. Algunos participantes consideraron las pruebas cerebrales necesarias para el diagnóstico diferencial. Un participante, determinado en incluir esta categoría, argumentó que la asociación de la enfermedad con una estructura corporal ayudaría a combatir el estigma al que están sometidas las personas que padecen de este trastorno.

Solo en uno de los estudios presentados, el "survey" con expertos, categorías del apartado "estructuras corporales" tuvieron una frecuencia superior a 10%. No obstante, considerando los diferentes estudios y los datos empíricos recogidos a través de la "Checklist de la CIF", 25 categorías distintas en el segundo nivel de la clasificación fueron enlazadas a los datos recogidos, estando representadas categorías de los capítulos s1 al s8 de la CIF.

Future Research Directions

Taking the results obtained, the following research directions are recommended:

- To perform an empirical cross-sectional study with bipolar disorder patients, collecting data from clinical assessments performed by the health professional responsible for the treatment of the individual patients and linking these to the ICF using the predefined linking rules, instead of using the ICF checklist, to avoid bias and have more comprehensive data on functioning in the way that it obtained in the different studies to allow more accurate comparisons between the different perspectives.
- To implement and perform validations studies of the ICF Core Sets for BD worldwide and eventually introduce changes to this first version according to the results obtained in these studies.
- To perform a study regarding the perspective of significant others, such as spouses and parents of individuals with BD and incorporate it into the ICF Core Sets for BD.
- To use the ICF and the first version of the ICF Core Sets for BD to develop a manual to be used in clinical practice on an everyday basis. This might give an input to integrate the impact of functioning from the ICF to the ICD-11.

Conclusions

- Most of the studies performed with bipolar patients concentrate on body functions rather than activities and participation domains. Experimental studies are mostly pharmacological studies, reflecting the need to study non-pharmacological interventions.
- Almost half of the participants mentioned having difficulties in the recreational area as well as in the establishment and maintenance of intimate relationships.
- Experts around the world are much aware of the impact of the environmental factors in functioning and disability. They are also considered important to assess activities and participation in their patients.
- The ICF makes it possible to link data across conditions or interventions for an efficient, transparent, and cost-effective health care.
- The ICF and the ICF Core Sets may indeed become the new base for the further development of such measures and also for example for item banking relevant to people with BD.
- A general reference framework may as well be powerful with regard to the communication between health professionals within specific settings but also when communicating between health professionals and patients and between settings. Because the ICF is etiologically neutral, it is easily possible to combine the ICF Core Sets for BD with other ICF Core Sets in a non-redundant and useful way when describing and classifying functioning and disability of people with more than just one condition.

Reference List

Akiskal, H. S., Bourgeois, M. L., Angst, J., Post, R., Moller, H., & Hirschfeld, R. (2000). Re-evaluating the prevalence of and diagnostic composition within the broad clinical spectrum of bipolar disorders. J.Affect.Disord., 59 Suppl 1, S5-S30.

American Psychiatry Association. (1994a). Diagnostic and statistical manual of mental disorders: DSM-IV (Vol. 4th). Washington, DC.: American Psychiatric Press, Inc.

American Psychiatry Association. (1994b). Global Assessment of Functioning Diagnostic and statistical manual of mental disorders: DSM-IV (Vol. 4th). Washington, DC.: American Psychiatric Press, Inc.

Berns, S., Uzelac, S., Gonzalez, C., & Jaeger, J. (2007). Methodological considerations of measuring disability in bipolar disorder: validity of the Multidimensional Scale of Independent Functioning. Bipolar Disord, 9(17391344), 3-10.

Bickenbach, J. E., Chatterji, S., Badley, E. M., & Ustun, T. B. (1999). Models of disablement, universalism and the international classification of impairments, disabilities and handicaps. Soc Sci Med, 48(10220018), 1173-1187.

Boake, C. (2002). From the Binet-Simon to the Wechsler-Bellevue: tracing the history of intelligence testing. J Clin Exp Neuropsychol, 24(3), 383-405.

Boldt, C., Brach, M., Grill, E., Berthou, A., Meister, K., Scheuringer, M., et al. (2005). The ICF categories identified in nursing interventions administered to neurological patients with post-acute rehabilitation needs. Disabil Rehabil, 27(16040546), 431-436.

Brockow, T., Cieza, A., Kuhlow, H., Sigl, T., Franke, T., Harder, M., et al. (2004). Identifying the concepts contained in outcome measures of clinical trials on musculoskeletal disorders and chronic widespread pain using the International Classification of Functioning, Disability and Health as a reference. J Rehabil Med(15370745), 30-36.

Brockow, T., Duddeck, K., Geyh, S., Schwarzkopf, S., Weigl, M., Franke, T., et al. (2004). Identifying the concepts contained in outcome measures of clinical trials on breast cancer using the International Classification of Functioning, Disability and Health as a reference. J Rehabil Med(15370747), 43-48.

Brockow, T., Wohlfahrt, K., Hillert, A., Geyh, S., Weigl, M., Franke, T., et al. (2004). Identifying the concepts contained in outcome measures of clinical trials on depressive disorders using the International Classification of Functioning, Disability and Health as a reference. J.Rehabil.Med.(44 Suppl), 49-55.

Bronfenbrenner, U. (1973). Developmental research and public policy. Res Publ Assoc Res Nerv Ment Dis, 51, 352-380.

Bronfenbrenner, U. (1997). Ecological systems theory. In R. Vast (Ed.), Six theories of child development (Vol. 2nd, pp. 187-249). Pennsylvania: Jessica Kingsley Publishers Ltd.

Bronfenbrenner, U., & Ceci, S. J. (1994). Nature-nurture reconceptualized in developmental perspective: a bioecological model. Psychol Rev, 101(4), 568-586.

Carr, A., Hewlett, S., Hughes, R., Mitchell, H., Ryan, S., Carr, M., et al. (2003). Rheumatology outcomes: the patient's perspective. J Rheumatol, 30(12672221), 880-883.

Chisholm, D., van Ommeren, M., Ayuso-Mateos, J.-L., & Saxena, S. (2005). Cost-effectiveness of clinical interventions for reducing the global burden of bipolar disorder. Br J Psychiatry, 187(16319409), 559-567.

Cieza, A., Brockow, T., Ewert, T., Amman, E., Kollerits, B., Chatterji, S., et al. (2002a). Linking health-status measurements to the international classification of functioning, disability and health. J.Rehabil.Med., 34(5), 205-210.

Cieza, A., Brockow, T., Ewert, T., Amman, E., Kollerits, B., Chatterji, S., et al. (2002b). Linking health-status measurements to the international classification of functioning, disability and health. Journal of Rehabilitation Medicine, 34(5), 205-210.

Cieza, A., Chatterji, S., Andersen, C., Cantista, P., Herceg, M., Melvin, J., et al. (2004). ICF Core Sets for depression. J Rehabil Med(15370760), 128-134.

Cieza, A., Ewert, T., Ustun, B., Chatterji, S., Konstansjek, N., & Stucki, G. (2004). Development of ICF core sets for patients with chronic conditions. Journal of Rehabilitation Medicine, Suppl 44(3), 9-11.

Cieza, A., Geyh, S., Chatterji, S., Kostanjsek, N., Üstün, B., & Stucki, G. (2005). ICF linking rules: an update based on lessons learned. Journal of Rehabilitation Medicine, 37, 1-8.

Cieza, A., Geyh, S., Chatterji, S., Kostanjsek, N., Ustun, B., & Stucki, G. (2005). ICF linking rules: an update based on lessons learned. J.Rehabil.Med., 37(4), 212-218.

Cieza, A., Geyh, S., Chatterji, S., Kostanjsek, N., Ustun, B., & Stucki, G. (2005). ICF linking rules: an update based on lessons learned. J Rehabil Med, 37(16024476), 212-218.

Cieza A, S. G. (2007). Applying the ICF and ICF Core Sets for chronic widespread pain. In C. D. Wittink H (Ed.), Pain management: Evidence, outcomes, and quality of life. A sourcebook. (pp. 161-170): Elsevier Limited

Cieza, A., & Stucki, G. (2004). New approaches to understanding the impact of musculoskeletal conditions. Best Pract Res Clin Rheumatol, 18(2), 141-154.

Cieza, A., & Stucki, G. (2005). Understanding functioning, disability, and health in rheumatoid arthritis: the basis for rehabilitation care. Curr Opin Rheumatol, 17(15711233), 183-189.

Colom, F., Vieta, E., Reinares, M., Martinez-Aran, A., Torrent, C., Goikolea, J. M., et al. (2003). Psychoeducation efficacy in bipolar disorders: beyond compliance enhancement. J Clin Psychiatry, 64(14628987), 1101-1105.

Coryell, W., Scheftner, W., Keller, M., Endicott, J., Maser, J., & Klerman, G. L. (1993). The enduring psychosocial consequences of mania and depression. Am.J.Psychiatry, 150(5), 720-727.

Cronbach, L. J., & Meehl, P. E. (1955). Construct validity in psychological tests. Psychol Bull, 52(13245896), 281-302.

de Graaf, L. E., Roelofs, J., & Huibers, M. J. (2009). Measuring Dysfunctional Attitudes in the General Population: The Dysfunctional Attitude Scale (form A) Revised. Cognit Ther Res, 33(4), 345-355.

De Lisio, G., Maremmani, I., Perugi, G., Cassano, G. B., Deltito, J., & Akiskal, H. S. (1986). Impairment of work and leisure in depressed outpatients. A preliminary communication. J Affect Disord, 10(2873159), 79-84.

Dean, B. B., Gerner, D., & Gerner, R. H. (2004). A systematic review evaluating health-related quality of life, work impairment, and healthcare costs and utilization in bipolar disorder. Curr.Med.Res.Opin., 20(2), 139-154.

Delbecq, A., Van de Ven, A., & Gustofon, D. (1975). Group Techniques for Program Planning. A guide to nominal group and delphi processes. Glenview, Illinois: Scott, Foresman and Company.

Denicoff, K. D., Smith-Jackson, E. E., Disney, E. R., Suddath, R. L., Leverich, G. S., & Post, R. M. (1997). Preliminary evidence of the reliability and validity of the prospective life-chart methodology (LCM-p). J Psychiatr Res, 31(9368200), 593-603.

Depp, C. A., Davis, C. E., Mittal, D., Patterson, T. L., & Jeste, D. V. (2006). Health-related quality of life and functioning of middle-aged and elderly adults with bipolar disorder. J Clin Psychiatry, 67(2), 215-221.

Dias, V. V., Brissos, S., Frey, B. N., & Kapczinski, F. (2008). Insight, quality of life and cognitive functioning in euthymic patients with bipolar disorder. J Affect Disord, 110(1-2), 75-83.

Endicott, J., Nee, J., Harrison, W., & Blumenthal, R. (1993). Quality of Life Enjoyment and Satisfaction Questionnaire: a new measure. Psychopharmacol Bull, 29(8290681), 321-326.

Endicott, J., Spitzer, R. L., Fleiss, J. L., & Cohen, J. (1976). The global assessment scale. A procedure for measuring overall severity of psychiatric disturbance. Arch Gen Psychiatry, 33(938196), 766-771.

Ewert, T., Fuessl, M., Cieza, A., Andersen, C., Chatterji, S., Kostanjsek, N., et al. (2004). Identification of the most common patient problems in patients with chronic conditions using the ICF checklist. J Rehabil Med(15370744), 22-29.

Finger, M. E., Cieza, A., Stoll, J., Stucki, G., & Huber, E. O. (2006). Identification of intervention categories for physical therapy, based on the international classification of functioning, disability and health: a Delphi exercise. Phys.Ther., 86(9), 1203-1220.

Fischer, K., & Bidell, T. (1998). Dynamic development of psychological structures in action and thought. In R. Lerner (Ed.), Handbook of child psychology (5th ed., Vol. 1. Theoretical models of human development, pp. 467-561). New York: Wiley.

Gannon, B. N., B. (2007). The impact of disability transitions on social inclusion. Soc Sci Med, 64(7), 1425-1437.

Garin, O., Ayuso-Mateos, J. L., Almansa, J., Nieto, M., Chatterji, S., Vilagut, G., et al. Validation of the World Health Organization Disability Assessment Schedule (WHODAS-2) in patients with chronic diseases. Health Qual Life Outcomes, 8(1), 51.

Geyh, S., Cieza, A., Kollerits, B., Grimby, G., & Stucki, G. (2007). Content comparison of health-related quality of life measures used in stroke based on the international classification of functioning, disability and health (ICF): a systematic review. Qual.Life Res., 16(5), 833-851.

Giacomini, M. K., & Cook, D. J. (2000). Users' guides to the medical literature: XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? Evidence-Based Medicine Working Group. JAMA, 284(10904512), 478-482.

Goldberg, J. F., & Burdick, K. E. (2008). Cognitive dysfunction in bipolar disorder: A guide for clinicians. Arlington: American Psychiatric Publishing, Inc.

Goodwin, G. M., Martinez-Aran, A., Glahn, D. C., & Vieta, E. (2008). Cognitive impairment in bipolar disorder: neurodevelopment or neurodegeneration? An ECNP expert meeting report. Eur.Neuropsychopharmacol., 18(11), 787-793.

Grill, E., Ewert, T., Chatterji, S., Kostanjsek, N., & Stucki, G. (2005a). ICF Core Set development for the acute hospital and early post-acute rehabilitation facilities. Disability and Rehabilitation, 27(7/8), 361-366.

Grill, E., Ewert, T., Chatterji, S., Kostanjsek, N., & Stucki, G. (2005b). ICF Core Sets development for the acute hospital and early post-acute rehabilitation facilities. Disabil Rehabil, 27(16040537), 361-366.

Hamilton, M. (1960). A rating scale for depression. J.Neurol.Neurosurg.Psychiatry, 23, 56-62.

Hirschfeld, R. M., Lewis, L., & Vornik, L. A. (2003). Perceptions and impact of bipolar disorder: how far have we really come? Results of the national depressive and manic-depressive association 2000 survey of individuals with bipolar disorder. J.Clin.Psychiatry, 64(2), 161-174.

Huxley, N., & Baldessarini, R. J. (2007). Disability and its treatment in bipolar disorder patients. Bipolar.Disord., 9(1-2), 183-196.

Jaeger, J., Berns, S., Loftus, S., Gonzalez, C., & Czobor, P. (2007). Neurocognitive test performance predicts functional recovery from acute exacerbation leading to hospitalization in bipolar disorder. Bipolar Disord, 9(17391353), 93-9102.

Jaeger, J., & Vieta, E. (2007). Functional outcome and disability in bipolar disorders: ongoing research and future directions. Bipolar.Disord., 9(1-2), 1-2.

Jerosch-Herold, C., Leite, J. C. d. C., & Song, F. (2006). A systematic review of outcomes assessed in randomized controlled trials of surgical interventions for carpal tunnel syndrome using the International Classification of Functioning, Disability and Health (ICF) as a reference tool. BMC Musculoskelet Disord, 7(17147807), 96-96.

Johnson, L., Lundstrom, O., berg-Wistedt, A., & Mathe, A. A. (2003). Social support in bipolar disorder: its relevance to remission and relapse. Bipolar.Disord., 5(2), 129-137.

Karlsson, G. (1995). Psychological Qualitative Research from a Phenomenological Perspective. Stockholm: Almquist & Wiskell International.

Keith, R. A., Granger, C. V., Hamilton, B. B., & Sherwin, F. S. (1987). The functional independence measure: a new tool for rehabilitation. Adv Clin Rehabil, 1(3503663), 6-18.

Kennedy, C. (2003). Functioning and disability associated with mental disorders: the evolution since ICIDH. Disabil Rehabil, 25(12959335), 611-619.

Kuhn, T.S. *The Structure of Scientific Revolutions*, 2nd. Ed., University of Chicago Press, Chicago, 1970

Kupfer, D. J. (2005). The increasing medical burden in bipolar disorder. JAMA, 293(15914754), 2528-2530.

Lehman, A. F. (1983). The well-being of chronic mental patients. Arch Gen Psychiatry, 40(6838316), 369-373.

Leon, A. C., Solomon, D. A., Mueller, T. I., Turvey, C. L., Endicott, J., & Keller, M. B. (1999). The Range of Impaired Functioning Tool (LIFE-RIFT): a brief measure of functional impairment. Psychol Med, 29(10473314), 869-878.

Leonardi, M., Bickenbach, J., Raggi, A., Sala, M., Guzzon, P., Valsecchi, M. R., et al. (2005). Training on the International Classification of Functioning, Disability and Health (ICF): the ICF-DIN Basic and the ICF-DIN Advanced Course developed by the Disability Italian Network. J Headache Pain, 6(3), 159-164.

MacQueen, G. M., Young, L. T., & Joffe, R. T. (2001). A review of psychosocial outcome in patients with bipolar disorder. Acta Psychiatr Scand, 103(11240572), 163-170.

Mahoney, F. I., & Barthel, D. W. (1965). FUNCTIONAL EVALUATION: THE BARTHEL INDEX. Md State Med J, 14(14258950), 61-65.

Martinez-Aran, A., Vieta, E., Colom, F., Torrent, C., Sanchez-Moreno, J., Reinares, M., et al. (2004). Cognitive impairment in euthymic bipolar patients: implications for clinical and functional outcome. Bipolar.Disord., 6(3), 224-232.

Martinez-Aran, A., Vieta, E., Reinares, M., Colom, F., Torrent, C., Sanchez-Moreno, J., et al. (2004). Cognitive function across manic or hypomanic, depressed, and euthymic states in bipolar disorder. Am J Psychiatry, 161(14754775), 262-270.

Martinez-Aran, A., Vieta, E., Torrent, C., Sanchez-Moreno, J., Goikolea, J. M., Salamero, M., et al. (2007). Functional outcome in bipolar disorder: the role of clinical and cognitive factors. Bipolar Disord, 9(17391354), 103-113.

Michalak, E. E., Yatham, L. N., Kolesar, S., & Lam, R. W. (2006). Bipolar disorder and quality of life: a patient-centered perspective. Qual.Life Res., 15(1), 25-37.

Microsoft Excel Professional, E. (2003). Microsoft© Excel 2003: Microsoft Corporation.

Morselli, P. L., Elgie, R., & Cesana, B. M. (2004). GAMIAN-Europe/BEAM survey II: cross-national analysis of unemployment, family history, treatment satisfaction and impact of the bipolar disorder on life style. Bipolar.Disord., 6(6), 487-497.

Mur, M., Portella, M. J., Martinez-Aran, A., Pifarre, J., & Vieta, E. (2009). Influence of clinical and neuropsychological variables on the psychosocial and occupational outcome of remitted bipolar patients. Psychopathology, 42(3), 148-156.

Otto, M. W., Perlman, C. A., Wernicke, R., Reese, H. E., Bauer, M. S., & Pollack, M. H. (2004). Posttraumatic stress disorder in patients with bipolar disorder: a review of prevalence, correlates, and treatment strategies. Bipolar.Disord., 6(6), 470-479.

Paykel, E. S. (1992). Handbook of affective disorders (Vol. 2nd). London: Guilford Press.

Perlick, D. A., Hohenstein, J. M., Clarkin, J. F., Kaczynski, R., & Rosenheck, R. A. (2005). Use of mental health and primary care services by caregivers of patients with bipolar disorder: a preliminary study. Bipolar.Disord., 7(2), 126-135.

Perugi, G., Maremmani, I., McNair, D. M., Cassano, G. B., & Akiskal, H. S. (1988). Differential changes in areas of social adjustment from depressive episodes through recovery. J Affect Disord, 15(2970491), 39-43.

Piaget, J. (1962). The stages of the intellectual development of the child. Bull Menninger Clin, 26, 120-128.

Piaget, J., & Inhelder, B. (1947). Diagnosis of mental operations and theory of the intelligence. Am J Ment Defic, 51(3), 401-406.

Piccinni, A., Catena, M., Del Debbio, A., Marazziti, D., Monje, C., Schiavi, E., et al. (2007). Health-related quality of life and functioning in remitted bipolar I outpatients. Compr Psychiatry, 48(4), 323-328.

Pope, C., Ziebland, S., & Mays, N. (2000). Qualitative research in health care. Analysing qualitative data. BMJ, 320(10625273), 114-116.

Posl, M., Cieza, A., & Stucki, G. (2007). Psychometric properties of the WHODASII in rehabilitation patients. Qual Life Res, 16(17828578), 1521-1531.

Robb, J. C., Cooke, R. G., Devins, G. M., Young, L. T., & Joffe, R. T. (1997). Quality of life and lifestyle disruption in euthymic bipolar disorder. J.Psychiatr.Res., 31(5), 509-517.

Rosa, A. R., Sanchez-Moreno, J., Martinez-Aran, A., Salamero, M., Torrent, C., Reinares, M., et al. (2007). Validity and reliability of the Functioning Assessment Short Test (FAST) in bipolar disorder. Clin.Pract.Epidemol.Ment.Health, 3, 5.

Sameroff, A. J. (1986). Environmental context of child development. J Pediatr, 109(1), 192-200.

Sameroff, A. J. (1992). Systems, development, and early intervention. Monogr Soc Res Child Dev, 57(6), 154-163.

Sameroff, A. J., & Mackenzie, M. J. (2003). Research strategies for capturing transactional models of development: the limits of the possible. Dev Psychopathol, 15(3), 613-640.

Sanchez-Moreno, J., Martinez-Aran, A., Tabares-Seisdedos, R., Torrent, C., Vieta, E., & Ayuso-Mateos, J. L. (2009). Functioning and Disability in Bipolar Disorder: An Extensive Review. Psychother Psychosom, 160 (in press).

Saxena, S., & Orley, J. (1997). Quality of life assessment: The world health organization perspective. Eur Psychiatry, 12S3, 263s-266s.

Sofaer, S. (1999). Qualitative methods: what are they and why use them? Health Serv.Res., 34(5 Pt 2), 1101-1118.

. SPSS (Version 16). (2007). Chicago, USA: SPSS Inc.

Stucki, G. (2005). International Classification of Functioning, Disability, and Health (ICF): a promising framework and classification for rehabilitation medicine. Am J Phys Med Rehabil, 84(16205428), 733-740.

Stucki, G., Boonen, A., Tugwell, P., Cieza, A., & Boers, M. (2007). The World Health Organization International Classification of Functioning, Disability

and Health: a conceptual model and interface for the OMERACT process. J Rheumatol, 34(17343306), 600-606.

Stucki, G., Cieza, A., Ewert, T., Kostanjsek, N., Chatterji, S., & Ustun, T. (2002). Application of the International Classification of Functioning, Disability and Health (ICF) in clinical practice. Disability and Rehabilitation, 24, 281-282.

Stucki, G., Cieza, A., & Melvin, J. (2007). The International Classification of Functioning, Disability and Health (ICF): a unifying model for the conceptual description of the rehabilitation strategy. J Rehabil Med, 39(4), 279-285.

Stucki, G., Ewert, T., & Cieza, A. (2002). Value and application of the ICF in rehabilitation medicine. Disability and Rehabilitation, 24(17), 932-938.

Stucki, G., & Grimby, G. (2004). Foreword: Applying the ICF in medicine. Journal of Rehabilitation Medicine, Suppl 44(3), 5-6.

Stucki, G., Stier-Jarmer, M., Grill, E., & Melvin, J. (2005a). Rationale and principles of early rehabilitation care after an acute injury or illness. Disabil Rehabil, 27(16040536), 353-359.

Stucki, G., Stier-Jarmer, M., Grill, E., & Melvin, J. (2005b). Rationale and principles of early rehabilitation care provision after an acute injury or illness. Disability and Rehabilitation, 27(7/8), 353-360.

Stucki, G., Ustun, B., & Melvin, J. (2005). Applying the ICF for the acute hospital and early postacute facilities. Disability and Rehabilitation, 27(7/8), 349-352.

Suppes T, D. E., Gibbons EW. (2000). The longitudinal course of bipolar disorder. J Clin Psychiatry, 61 (Suppl. 9), 23-30.

Thomas, P. (2004). The many forms of bipolar disorder: a modern look at an old illness. J.Affect.Disord., 79 Suppl 1, S3-S8.

Tschiesner, U. M., Rogers, S. N., Harreus, U., Berghaus, A., & Cieza, A. (2009). Comparison of outcome measures in head and neck cancer--literature review 2000-2006. Head Neck, 31(2), 251-259.

Ustun, B., Chatterji, S., & Konstansjek, N. (2004). Comments from WHO for the Journal of Rehabilitation Medicine special supplement on ICF Core Sets. Journal of Rehabilitation Medicine, Suppl 44(3), 7-8.

Vieta, E., Cieza, A., Stucki, G., Chatterji, S., Nieto, M., Sanchez-Moreno, J., et al. (2007). Developing core sets for persons with bipolar disorder based on the International Classification of Functioning, Disability and Health. Bipolar.Disord., 9(1-2), 16-24.

Vieta, E., Colom, F., Martinez-Aran, A., Benabarre, A., Reinares, M., & Gasto, C. (2000). Bipolar II disorder and comorbidity. Compr Psychiatry, 41(11011829), 339-343.

Ware, J. E., & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care, 30(1593914), 473-483.

Wechsler, D. (1995). Wechsel Adult Intelligence Scale - Revised. Psychological Corporation.

Weigl, M., Cieza, A., Andersen, C., Kollerits, B., Amann, E., & Stucki, G. (2004). Identification of relevant ICF categories in patients with chronic health conditions: a Delphi exercise. J Rehabil Med(44 Suppl), 12-21.

Weigl, M., Cieza, A., Cantista, P., Reinhardt, J. D., & Stucki, G. (2008). Determinants of disability in chronic musculoskeletal health conditions: a literature review. Eur.J.Phys.Rehabil.Med., 44(1), 67-79.

Weissman, M. M., Bland, R. C., Canino, G. J., Faravelli, C., Greenwald, S., Hwu, H. G., et al. (1996). Cross-national epidemiology of major depression and bipolar disorder. JAMA, 276(4), 293-299.

Weston, W. W. (2001). Informed and shared decision-making: the crux of patient-centered care. Cmaj, 165(4), 438-439.

Wolff, B., Cieza, A., Parentin, A., Rauch, A., Sigl, T., Brockow, T., et al. (2004). Identifying the concepts contained in outcome measures of clinical trials on four internal disorders using the International Classification of Functioning, Disability and Health as a reference. J Rehabil Med(15370746), 37-42.

World Health Organization. (1992). International Classification of Diseases 10: ICD-10: World Health Organization.

World Health Organization. (1996). International Statistical Classification of Diseases and related health problems: 10th revision (ICD-10). Geneva: World Health Organization.

World Health Organization, The World Health Organization Quality of Life Assessment (WHOQOL): development and general psychometric properties. (1998). Soc Sci Med, 46(12), 1569-1585.

World Health Organization. (2001). International Classification of Functioning, Disability and Health: ICF. Geneva: WHO.

World Health Organization (2001b). ICF Checklist Version 2.1a. Clinical Form for International Classification of Functioning. Disability and Health: ICF. Geneva: WHO Library Cataloguing-in-Publication Data:.

World Health Organization. (2001c). World Health Report 2001.Mental Health: New Understanding, New Hope. Geneva.

Wyatt, R. J., & Henter, I. (1995). An economic evaluation of manic-depressive illness--1991. Soc Psychiatry Psychiatr Epidemiol, 30(7482006), 213-219.

Young, R. C., Biggs, J. T., Ziegler, V. E., & Meyer, D. A. (1978). A rating scale for mania: reliability, validity and sensitivity. Br.J.Psychiatry, 133, 429-435.

Zimet, G. D., Powell, S. S., Farley, G. K., Werkman, S., & Berkoff, K. A. (1990). Psychometric characteristics of the Multidimensional Scale of Perceived Social Support. J Pers Assess, 55(3-4), 610-617.

APPENDIX A: THE ICF CHECKLIST

ICF CHECKLIST

Version 2.1a, Clinician Form

for International Classification of Functioning, Disability and Health

This is a checklist of major categories of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization . The ICF Checklist is a practical tool to elicit and record information on the functioning and disability of an individual. This information can be summarized for case records (for example, in clinical practice or social work). The checklist should be used along with the ICF or ICF Pocket version.

H 1. When completing this checklist, use all information available. Please check those used:
[1] written records [2] primary respondent [3] other informants [4] direct observation

If medical and diagnostic information is not available it is suggested to complete appendix 1: Brief Health Information (p 9-10) which can be completed by the respondent.

H 2. Date __ __ /__ __/__ __ ***H 3. Case ID*** _ _ , __ __ __ , __ ***H 4. Participant No.*** __ __ , __ __ , __ __ __
Day Month Year CE or CS Case No. 1st or 2nd Evalu FTC Site Participant

A. DEMOGRAPHIC INFORMATION

A.1 NAME *(optional)* First _____ FAMILY_____

A.2 SEX (1) [ ] Female (2) [ ] Male

A.3 DATE OF BIRTH _ _/_ _/_ _ *(date/month/year)*

A.4 ADDRESS *(optional)*

A.5 YEARS OF FORMAL EDUCATION _ _

A.6 CURRENT MARITAL STATUS: *(Check only one that is most applicable)*

(1) Never married	[ ]	(4) Divorced	[ ]
(2) Currently Married	[ ]	(5) Widowed	[ ]
(3) Separated	[ ]	(6) Cohabiting	[ ]

A.7 CURRENT OCCUPATION *(Select the single best option)*

(1) Paid employment	[ ]	(6) Retired	[ ]
(2) Self-employed	[ ]	(7) Unemployed (health reason)	[ ]
(3) Non-paid work, such as volunteer/charity	[ ]	(8) Unemployed (other reason)	[ ]
(4) Student	[ ]	(9) Other	[ ]
(5) Keeping house/House-maker	[ ]	*(please specify)* _____	

A.8 MEDICAL DIAGNOSIS of existing Main Health Conditions, ***if possible give ICD Codes.***

1. No Medical Condition exists
2. …….. ICD code: __. __. __.__. __
3. …….. ICD code: __. __. __.__. __
4. …….. ICD code: __. __. __.__. __
5. A Health Condition (disease, disorder, injury) exists, however its nature or diagnosis is not known

PART 1a: IMPAIRMENTS of BODY FUNCTIONS

- Body functions are the physiological functions of body systems (including psychological functions).
- Impairments are problems in body function as a significant deviation or loss.

First Qualifier: *Extent of impairments*
0 No impairment means the person has no problem ***1 Mild impairment*** means a problem that is present less than 25% of the time, with an intensity a person can tolerate and which happens rarely over the last 30 days. ***2 Moderate impairment*** means that a problem that is present less than 50% of the time, with an intensity, which is interfering in the persons day to day life and which happens occasionally over the last 30 days. ***3 Severe impairment*** means that a problem that is present more than 50% of the time, with an intensity, which is partially disrupting the persons day to day life and which happens frequently over the last 30 days. ***4 Complete impairment*** means that a problem that is present more than 95% of the time, with an intensity, which is totally disrupting the persons day to day life and which happens every day over the last 30 days. ***8 Not specified*** means there is insufficient information to specify the severity of the impairment. ***9 Not applicable*** means it is inappropriate to apply a particular code (e.g. b650 Menstruation functions for woman in pre-menarche or post-menopause age).

Short List of Body Functions	***Qualifier***
b1. MENTAL FUNCTIONS	
b110 Consciousness	
b114 Orientation *(time, place, person)*	
b117 Intellectual *(incl. Retardation, dementia)*	
b130 Energy and drive functions	
b134 Sleep	
b140 Attention	
b144 Memory	
b152 Emotional functions	
b156 Perceptual functions	
b164 Higher level cognitive functions	
b167 Language	
b2. SENSORY FUNCTIONS AND PAIN	
b210 Seeing	
b230 Hearing	
b235 Vestibular *(incl. Balance functions)*	
b280 Pain	
b3. VOICE AND SPEECH FUNCTIONS	
b310 Voice	
b4. FUNCTIONS OF THE CARDIOVASCULAR, HAEMATOLOGICAL, IMMUNOLOGICAL AND RESPIRATORY SYSTEMS	
b410 Heart	
b420 Blood pressure	
b430 Haematological *(blood)*	
b435 Immunological *(allergies, hypersensitivity)*	
b440 Respiration *(breathing)*	
b5. FUNCTIONS OF THE DIGESTIVE, METABOLIC AND ENDOCRINE SYSTEMS	
b515 Digestive	
b525 Defecation	
b530 Weight maintenance	
b555 Endocrine glands *(hormonal changes)*	
b6. GENITOURINARY AND REPRODUCTIVE FUNCTIONS	
b620 Urination functions	

b640 Sexual functions	
b7. NEUROMUSCULOSKELETAL AND MOVEMENT RELATED FUNCTIONS	
b710 Mobility of joint	
b730 Muscle power	
b735 Muscle tone	
b765 Involuntary movements	
b8. FUNCTIONS OF THE SKIN AND RELATED STRUCTURES	
ANY OTHER BODY FUNCTIONS	

Part 1 b: IMPAIRMENTS of BODY STRUCTURES

- Body structures are anatomical parts of the body such as organs, limbs and their components.
- Impairments are problems in structure as a significant deviation or loss.

First Qualifier: ***Extent of impairment***	**Second Qualifier:** ***Nature of the change***
0 No impairment means the person has no problem ***1 Mild impairment*** means a problem that is present less than 25% of the time, with an intensity a person can tolerate and which happens rarely over the last 30 days. ***2 Moderate impairment*** means that a problem that is present less than 50% of the time, with an intensity, which is interfering in the persons day to day life and which happens occasionally over the last 30 days. ***3 Severe impairment*** means that a problem that is present more than 50% of the time, with an intensity, which is partially disrupting the persons day to day life and which happens frequently over the last 30 days. ***4 Complete impairment*** means that a problem that is present more than 95% of the time, with an intensity, which is totally disrupting the persons day to day life and which happens every day over the last 30 days. ***8 Not specified*** means there is insufficient information to specify the severity of the impairment. ***9 Not applicable*** means it is inappropriate to apply a particular code (e.g. b650 Menstruation functions for woman in pre-menarche or post-menopause age).	**0** No change in structure **1** Total absence **2** Partial absence **3** Additional part **4** Aberrant dimensions **5** Discontinuity **6** Deviating position **7** Qualitative changes in structure, including accumulation of fluid **8** Not specified **9** Not applicable

Short List of Body Structures	**First Qualifier:** ***Extent of impairment***	**Second Qualifier:** ***Nature of the change***
s1. STRUCTURE OF THE NERVOUS SYSTEM		
s110 Brain		
s120 Spinal cord and peripheral nerves		
s2. THE EYE, EAR AND RELATED STRUCTURES		
s3. STRUCTURES INVOLVED IN VOICE AND SPEECH		
s4. STRUCTURE OF THE CARDIOVASCULAR, IMMUNOLOGICAL AND RESPIRATORY SYSTEMS		
s410 Cardiovascular system		
s430 Respiratory system		
s5. STRUCTURES RELATED TO THE DIGESTIVE, METABOLISM AND ENDOCRINE SYSTEMS		

s6. STRUCTURE RELATED TO GENITOURINARY AND REPRODUCTIVE SYSTEM		
s610 Urinary system		
s630 Reproductive system		
s7. STRUCTURE RELATED TO MOVEMENT		
s710 Head and neck region		
s720 Shoulder region		
s730 Upper extremity *(arm, hand)*		
s740 Pelvis		
s750 Lower extremity *(leg, foot)*		
s760 Trunk		
s8. SKIN AND RELATED STRUCTURES		
ANY OTHER BODY STRUCTURES		

PART 2: ACTIVITY LIMITATIONS & PARTICIPATION RESTRICTION

- *Activity is the execution of a task or action by an individual.. Participation is involvement in a life situation.*
- *Activity limitations are difficulties an individual may have in executing activities. Participation restrictions are problems an individual may have in involvement in life situations.*

*The **Performance qualifier** indicates the **extent of Participation restriction** by describing the persons **actual performance** of a task or action **in his or her current environment.** Because the current environment brings in the societal context, performance can also be understood as "involvement in a life situation" or "the lived experience" of people in the actual context in which they live. This context includes the environmental factors – all aspects of the physical, social and attitudinal world that can be coded using the Environmental. The Performance qualifier measures the difficulty the respondent experiences in **doing things, assuming that they want to do them**.*

*The **Capacity qualifier** indicates the **extent of Activity limitation** by describing the **person ability** to execute a task or an action. The Capacity qualifier focuses on limitations that are inherent or intrinsic features of the person themselves. These limitations should be direct manifestations of the respondent's health state, **without the assistance**. By assistance we mean the help of another person, or assistance provided by an adapted or specially designed tool or vehicle, or any form of environmental modification to a room, home, workplace etc.. The level of capacity should be judged relative to that normally expected of the person, or the person's capacity before they acquired their health condition.*

Note: Use Appendix 2 if needed to elicit information on the Activities and Participation of the individual

First Qualifier: *Performance* *Extent of Participation Restriction*	**Second Qualifier:** *Capacity (without assistance)* *Extent of Activity limitation*
0 No difficulty means the person has no problem ***1 Mild difficulty*** means a problem that is present less than 25% of the time, with an intensity a person can tolerate and which happens rarely over the last 30 days. ***2 Moderate difficulty*** means that a problem that is present less than 50% of the time, with an intensity, which is interfering in the persons day to day life and which happens occasionally over the last 30 days. ***3 Severe difficulty*** means that a problem that is present more than 50% of the time, with an intensity, which is partially disrupting the persons day to day life and which happens frequently over the last 30 days. ***4 Complete difficulty*** means that a problem that is present more than 95% of the time, with an intensity, which is totally disrupting the persons day to day life and which happens every day over the last 30 days. ***8 Not specified*** means there is insufficient information to specify the severity of the difficulty. ***9 Not applicable*** means it is inappropriate to apply a particular code (e.g. b650 Menstruation functions for woman in pre-menarche or post-menopause age).	

Short List of A&P domains	*Performance Qualifier*	*Capacity Qualifier*
d1. LEARNING AND APPLYING KNOWLEDGE		
d110 Watching		
d115 Listening		
d140 Learning to read		
d145 Learning to write		
d150 Learning to calculate *(arithmetic)*		
d175 Solving problems		
d2. GENERAL TASKS AND DEMANDS		
d210 Undertaking a single task		
d220 Undertaking multiple tasks		
d3. COMMUNICATION		
d310 Communicating with -- receiving -- spoken messages		
d315 Communicating with -- receiving -- non-verbal messages		
d330 Speaking		
d335 Producing non-verbal messages		
d350 Conversation		
d4. MOBILITY		
d430 Lifting and carrying objects		
d440 Fine hand use *(picking up, grasping)*		
d450 Walking		
d465 Moving around using equipment *(wheelchair, skates, etc.)*		
d470 Using transportation *(car, bus, train, plane, etc.)*		
d475 Driving (riding bicycle and *motorbike, driving car, etc.)*		
d5. SELF CARE		
d510 Washing oneself *(bathing, drying, washing hands, etc)*		
d520 Caring for body parts *(brushing teeth, shaving, grooming, etc.)*		
d530 Toileting		
d540 Dressing		
d550 Eating		
d560 Drinking		
d570 Looking after one`s health		
d6. DOMESTIC LIFE		
d620 Acquisition of goods and services *(shopping, etc.)*		
d630 Preparation of meals *(cooking etc.)*		
d640 Doing housework *(cleaning house, washing dishes laundry, ironing, etc.)*		
d660 Assisting others		
d7. INTERPERSONAL INTERACTIONS AND RELATIONSHIPS		
d710 Basic interpersonal interactions		
d720 Complex interpersonal interactions		
d730 Relating with strangers		
d740 Formal relationships		
d750 Informal social relationships		
d760 Family relationships		
d770 Intimate relationships		
d8. MAJOR LIFE AREAS		

d810 Informal education		
d820 School education		
d830 Higher education		
d850 Remunerative employment		
d860 Basic economic transactions		
d870 Economic self-sufficiency		
d9. COMMUNITY, SOCIAL AND CIVIC LIFE		
d910 Community Life		
d920 Recreation and leisure		
d930 Religion and spirituality		
d940 Human rights		
d950 Political life and citizenship		
ANY OTHER ACTIVITY AND PARTICIPATION		

PART 3: ENVIRONMENTAL FACTORS

- *Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives.*

Qualifier in environment:	**0** No barriers	**0** No facilitator
Barriers or facilitator	**1** Mild barriers	+**1** Mild facilitator
	2 Moderate barriers	+**2** Moderate facilitator
	3 Severe barriers	+**3** Substantial facilitator
	4 Complete barriers	+**4** Complete facilitator

Short List of Environment	***Qualifier barrier or facilitator***
e1. PRODUCTS AND TECHNOLOGY	
e110 For personal consumption *(food, medicines)*	
e115 For personal use in daily living	
e120 For personal indoor and outdoor mobility and transportation	
e125 Products for communication	
e150 Design, construction and building products and technology of buildings for public use	
e155 Design, construction and building products and technology of buildings for private use	
e2. NATURAL ENVIRONMENT AND HUMAN MADE CHANGES TO ENVIRONMENT	
e225 Climate	
e240 Light	
e250 Sound	
e3. SUPPORT AND RELATIONSHIPS	
e310 Immediate family	
e320 Friends	
e325 Acquaintances, peers, colleagues, neighbours and community members	
e330 People in position of authority	
e340 Personal care providers and personal assistants	
e355 Health professionals	
e360 Health related professionals	
e4. ATTITUDES	
e410 Individual attitudes of immediate family members	
e420 Individual attitudes of friends	
e440 Individual attitudes of personal care providers and personal assistants	
e450 Individual attitudes of health professionals	
e455 Individual attitudes of health related professionals	
e460 Societal attitudes	
e465 Social norms, practices and ideologies	
E5. SERVICES, SYSTEMS AND POLICIES	
e525 Housing services, systems and policies	
e535 Communication services, systems and policies	
e540 Transportation services, systems and policies	
e550 Legal services, systems and policies	
e570 Social security, services, systems and policies	
e575 General social support services, systems and policies	
e580 Health services, systems and policies	
e585 Education and training services, systems and policies	
e590 Labour and employment services, systems and policies	
ANY OTHER ENVIRONMENTAL FACTORS	

Part 4: OTHER CONTEXTUAL INFORMATION

4. 1 *Give a thumbnail sketch of the individual and any other relevant information.*

4.2 *Include any* ***Personal Factors*** *as they impact on functioning (e.g. lifestyle, habits, social background, education, life events, race/ethnicity, sexual orientation and assets of the individual).*

Appendix 1:

BRIEF HEALTH INFORMATION

[ ] Self Report [ ] Clinician Administered

X.1 Height : __/__/__ cm *(or inches)*

X.2 Weight: __/__/__ kg *(or pounds)*

X.3 Dominant Hand *(prior to health condition)*: Left [ ] Right [ ] Both hands equally [ ]

X.4 How do you rate your physical health in the past month?

Very good [ ] Good [ ] Moderate [ ] Bad [ ] Very bad [ ]

X.5 How do you rate your mental and emotional health in the past month?

Very good [ ] Good [ ] Moderate [ ] Bad [ ] Very bad [ ]

X.6 Do you currently have any disease(s) or disorder(s) ?

[ ] NO [ ] YES

*If YES, please specify:*_____

_____

X.7 Did you ever have any significant injuries that had an impact on your level of functioning?

[ ] NO [ ] YES

If YES, please specify _____

_____

X.8 Have you been hospitalized in the last year?

[ ] NO [ ] YES

If YES, please specify reason(s) and for how long?

1. _____; ___. ___. ___ days
2. _____; ___. ___. ___ days
3. _____; ___. ___. ___ days

X.9 Are you taking any medication (either prescribed or over the counter)?

[ ] NO [ ] YES

If YES, please specify major medications

1. _____
2. _____
3. _____

X.10 Do you smoke?

[ ] NO [ ] YES

X.11 Do you consume alcohol or drugs?

[ ] NO [ ] YES

If YES, please specify average daily quantity

Tobacco: _____
Alcohol: _____
Drugs: _____

X.12 Do you use any assistive device such as glasses, hearing aid, wheelchair, etc.?

[ ] NO [ ] YES

If YES, please specify

_____

X.13 Do you have any person assisting you with your self care, shopping or other daily activities?

[ ] NO [ ] YES

If YES, please specify person and assistance they provide

_____

X.14 Are you receiving any kind of treatment for your health?

[ ] NO [ ] YES

If YES, please specify:

_____

X.15 Additional significant information on your past and present health:

_____

_____

X.16 IN THE PAST MONTH, have you cut back (i.e. reduced) your usual activities or work because of your *health condition*? (a disease, injury, emotional reasons or alcohol or drug use)

[ ] NO [ ] YES If yes, how many days? _____

X.17 IN THE PAST MONTH, have you been totally unable to carry out your usual activities or work because of your *health condition*? (a disease, injury, emotional reasons or alcohol or drug use)

[ ] NO [ ] YES If yes, how many days? _____

Appendix 2:

GENERAL QUESTIONS FOR PARTICIPATION & ACTIVITIES

The following probes are proposed as a guide to help the examiner when interviewing the respondent about problems in functioning and life activities, in terms of the distinction between capacity and performance Take into account all personal information known about the respondent and ask any additional probes as necessary. Probes should be rephrased as open-ended questions if necessary to elicit greater information.

Under each domain there are two kinds of probes:

*The first probe tries to get the respondent to focus on his or her **capacity** to do a task or action, and in particular to focus on limitations in capacity that are **inherent or intrinsic features of the person** themselves. These limitations should be direct manifestations of the respondent's health state, without the assistance. By **assistance** we mean the help of another person, or assistance provided by an adapted or specially designed tool or vehicle, or any form of environmental modification to a room, home, workplace and so o. The level of capacity should be judged relative to that normally expected of the person, or the person's capacity before they acquired their health condition.*

*The second probe focuses on the respondent's **actual performance** of a task or action in the person's actual situation or surroundings, and elicits information about the effects of environmental barriers or facilitators. It is important to emphasize that you are only interested in the extent of difficulty the respondent has in doing things, **assuming that they want to do them**. Not doing something is irrelevant if the person chooses not to do it.*

I. Mobility

(Capacity)

(1) In your present state of health, how much difficulty do you have walking long distances (such as a kilometer or more) without assistance?

(2) How does this compare with someone, just like yourself only without your health condition?

(Or: "…than you had before you developed your health problem or had the accident?)

(Performance)

(1) In your present surroundings, how much of a problem do you actually have in walking long distances (such as a kilometer or more)?

(2) Is this problem walking made worse, or better, by your actual surroundings?

(3) Is your capacity to walk long distances without assistance more or less than what you actually do in your present surroundings?

II. Self Care

(Capacity)

(1) In your present state of health, how much difficulty do you have washing yourself, without assistance?

(2) How does this compare with someone, just like yourself only without your health condition?

(Or: "…than you had before you developed your health problem or had the accident?)

(Performance)

(1) In your own home, how much of a problem do you actually have washing yourself?

(2) Is this problem made worse, or better, by the way your home is set up or the specially adapted tools you use?

(3) Is your capacity to wash yourself without assistance more or less than what you actually do in your present surroundings?

III. Domestic Life

(Capacity)

(1) In your present state of health, how much difficulty do you have cleaning the floor of your where you live, without assistance?

(2) How does this compare with someone, just like yourself only without your health condition?

(Or: "…than you had before you developed your health problem or had the accident?)

(Performance)

(1) In your own home, how much of a problem do you actually have cleaning the floor?

(2) Is this problem made worse, or better, by the way your home is set up or the specially adapted tools you use?

(3) Is your capacity to clean your floor without assistance more or less than what you actually do in your present surroundings?

IV. Interpersonal Interactions

(Capacity)

(1) In your present state of health, how much difficulty do you have making new friends, without assistance?

(2) How does this compare with someone, just like yourself only without your health condition?

(Or: "…than you had before you developed your health problem or had the accident?)

(Performance)

(1) In your present situation, how much of a problem do you actually have making friends?

(2) Is this problem making friends made worse, or better, by anything (or anyone) in your surroundings?

(3) Is your capacity to make friends, without assistance, more or less than what you actually do in your present surroundings?

V. Major Life Areas

(Capacity)

(1) In your present state of health, how much difficulty do you have getting done all the work you need to do for your job, without assistance?

(2) How does this compare with someone, just like yourself only without your health condition?

(Or: "…than you had before you developed your health problem or had the accident?)

(Performance)

(1) In your present surroundings, how much of a problem do you actually have getting done all the work you need to do for your job?

(2) Is this problem fulfilling your job requirements made worse, or better, by the way the work environment is set up or the specially adapted tools you use?

(3) Is your capacity to do your job, without assistance, more or less than what you actually do in your present surroundings?

VI. Community, Social and Civic Life

(Capacity)

(1) In your present state of health, how much difficulty do you have participating in community gatherings, festivals or other local events, without assistance?

(2) How does this compare with someone, just like yourself only without your health condition?

(Or: "…than you had before you developed your health problem or had the accident?)

(Performance)

(1) In your community, how much of a problem do you actually have participating in community gatherings, festivals or other local events?

(2) Is this problem made worse, or better, by the way your community is arranged or the specially adapted tools, vehicles or whatever you use?

(3) Is your capacity to participate in community events, without assistance, more or less than what you actually do in your present surroundings?

Appendix 3:

GUIDELINES FOR THE USE OF ICF CHECKLIST VERSION 2.1A

1. This is a checklist of major categories of International Classification of Functioning, Disability and Health (ICF) of the World Health Organization . The ICF Checklist is a practical tool to elicit and record information on the functioning and disability of an individual. This information can be summarized for case records (for example, in clinical practice or social work).

2. This version (2.1a) is for use by a clinician, health or social care professional.

3. The checklist should be used along with the ICF full or short version which is scheduled for publication in September 2001. Until then the ICIDH-2 Final Draft, full version, WHO, 2001 will serve as reference document for the ICF checklist. The raters should familiarize themselves with the ICIDH-2 Final Draft by attending a brief educational programme or self-taught curriculum.

4. All information from written records, primary respondent, other informants and direct observation can be used to fill in the checklist. Please record all sources of information used on the first page.

5. Parts 1 to 3 should be filled in by writing the qualifier code against each of the function, structure, activity and participation term that shows some problem for the case being evaluated. Appropriate codes for the qualifiers are given on the relevant pages.

6. Comments can be made regarding any information that can serve as the additional qualifier or that is thought to be significant for the case being evaluated.

7. Part 4 (Environment) has both negative (barrier)and positive (facilitator) qualifier codes. For all positive qualifier codes, please use a plus (+) sign before the code.

8. The categories given in the checklist have been selected from the ICF and are not exhaustive. If you need to use a category that you do not find listed here, use the space at the end of each dimension to record these.

APPENDIX B:

SOME OF THE DOCUMENTATION PROVIDED TO THE ICF CONSENSUS CONFERENCE PARTICIPANTS

Programme and general information

Decision-making and consensus process

Participants

Project team

Extract of an address
by the WHO Director-General regarding the ICF

Presentations

- **Introduction to the ICF:**
  An overview and exercise with case examples

- **The ICF project:**
  An overview of the preparatory studies

- **Introduction to decision - making & consensus process**

Candidate ICF categories - Individual Vote

Documentation of decision-making & consensus process

Publications

Copy of the ICF

Comments

Participants

Participants
ICF Consensus Conference

Alarcon, Renato
Psychiatrist
PsMood Disorders Unit, MPPTC
Mayo Clinic
Minnesota, USA

Bambrilla, Paolo
Psychiatrist
Pathology, Experimental and Clinical Medicine Department.
University of Udine, Via Colugna 50, 33100, Udine, Italy

Beentjes, Thitus A.A.
Nurse
Expert Centre Bipolar Disorders Pikeursbaan, 37411 GT
Deventer, The Netherlands

de Dios, Consuelo
Psychiatrist
Department of Psychiatry, Hospital Universitario de La Paz
Pº de la Castellana, 261, 28046 Madrid, Spain

Ezquiaga, Elena
Psychiatrist
Hospital Universitario de La princesa
Diego de León 62,
28006 Madrid, Spain

Gusmão, Ricardo
Psychiatrist
Mental Health Department
Medical Sciencies
Universidade Nova de Lisboa
Campo Mártires da Pátria, Nº 130
Lisbon, Portugal

Hegerl, Ulrich
Psychiatrist
University of Leipzig, Clinic and Policlinic for Psychiatry and Psychotherapy. Semmelweisstr. 10, 04103 Leipzig, Germany.

Heinze, Gerhard
Psychiatrist
Universidad Nacional Autónoma de México and Instituto Nacional de Psiquiatría Ramón de la Fuente, Calzada Mexico-Xochimilco, Col. San Lorenzo Huipulco, México, D.F. 14370 Mexico

Hernandez Matilde
Psychiatrist
Fundación Investigaciones Biomédicas
Hospital Universitario de la Princesa, Calle Diego de León 62, 28006, Madrid, Spain

Matsuo, Koji
Psychiatrist
Division of Neuropsychiatry, Department of Neuroscience, Yamaguchi University, Graduate School of Medicine, 1-1-1 Minamikogushi, Ube, Yamaguchi 755-8505, Japan

Leal, Itziar
Psychiatrist
Department of Psychiatry Universidad Autónoma de Madrid and Hospital Universitario de la Princesa, Calle Diego de León 62, 28006, Madrid, Spain

Lobban, Fiona
Psychologist
School of Health and Medicine
Lancaster University
Physics Building
Lancaster University
Lancaster
Lancashire
LA1 4YD - UK

Martínez-Arán, Anabel
Psychologist
Bipolar Disorders Program,
Department of Psychiatry and Clinical Psychology.
Hospital Clinic of Barcelona, Villarroel 170, 08036, Barcelona, Spain

Montes, José Manuel
Psychiatrist
Department of Psychiatry
Hospital del Sureste (Madrid), Ronda del Sur, 10, 28500, Arganda del Rey, Madrid, Spain

Pérez, Víctor
Psychiatrist
Psychiatry Department
Hospital de la Santa Creu i Sant Pau,
C/ Sant Antoni Maria Claret,167 08025 Barcelona, Spain

Ptyushkin, Pavel
Psychiatrist
MURINET Marie Curie Fellow
University Rehabilitation Institute of the Republic of Slovenia
Linhartova 51, 1000 Ljubljana, Slovenia

Sarin, Alok
Psychiatrist
Sitaram Bhartia Institute, Vimhans Hospital, B 16 Qutub Institutional Area, New Delhi, India

Sunbaunat, Ka
Psychiatrist
Psychiatry Department
University of Health Sciences
Preah Monyvong Blvd, Phnom Penh Cambodia

Raust, Aurélie
Psychologist
Pôle de psychiatrie (Pr Leboyer), Hôpital Albert Chenevier,
40 rue de Mesly, 94000 Créteil France

Torrent, Carla
Psychologist
Bipolar Disorders Program,
Department of Psychiatry and Clinical Psychology.
Hospital Clinic Barcelona,
Villarroel 170, 08036, Barcelona, Spain.

Valle, Jesús
Psychiatrist
Department of Psychiatry Universidad Autónoma de Madrid and Hospital Universitario de La Princesa, Diego de León 62, 28006 Madrid, Spain

Vázquez, Gustavo Héctor
Psychiatrist
Department of Neuroscience,
University of Palermo, Sánchez de Bustamante 2167. 7mo D,
Buenos Aires, Argentina

Project team

International Consensus Conference on Bipolar Disorders

Development of the first version of the ICF Core Sets for Bipolar Disorders.

May 13th to 15th 2010, Madrid, SPAIN
Facultad de Medicina, Universidad Autónoma de Madrid
Room : Pagoda
c/ Azobispo Morcillo sn

Steering Committee

Ayuso-Mateos, Jose Luis. Department of Psychiatry, Universidad Autónoma de Madrid y Hospital Universitario de la Princesa, Calle Diego de León 62, 28006, Madrid, Spain.Steering Committee Chair

Cieza, Alarcos. Institute for Health and Rehabilitation Sciences (IHRS), Ludwig-Maximilians-University (LMU), Marchioninistrasse 17, 81377 Munich, Germany. ICF Research Branch of the Collaborating Centre for the WHO Family of International Classification in German.

Vieta, **Eduard.** Bipolar Disorders Program, Department of Psychiatry and Clinical Psychology. Hospital Clinic of Barcelona, Villarroel 170, 08036, Barcelona, Spain.

Project Manager
Ávila, Carolina. Department of Psychiatry, Universidad Autónoma de Madrid. Spain.

Team
Universidad Autónoma de Madrid

Celia Anaya	*Psychologist* *University Autónoma of Madrid* *Madrid, Spain*
Carolina Ávila	*Psychologist* *MURINET Marie Curie Fellow* *University Autónoma of Madrid* *Madrid, Spain*
José Luis Ayuso-Mateos	*Psychiatrist* *University Autónoma of Madrid and* *University Hospital La Princesa* *Madrid, Spain*
Blanca Mellor	*Psychologist* *University Autónoma of Madrid* *Madrid, Spain*
Antonio Veronese	*Psychologist* *MURINET Marie Curie Fellow* *University Autónoma of Madrid* *Madrid, Spain*

Team

ICF Research Branch of the Collaborating Centre for the WHO Family of International Classifications in German

Jerome Bickenbach	*Philosopher & Lawyer* *Steering Committee member of the ICF Research Branch* *Swiss Paraplegic Research (SPF), Nottwil, Switzerland*
Cristina Bostan	*Statistician* *MURINET Marie Curie Fellow* *Institute for Health and Rehabilitation Sciences (IHRS)* *Unit for Biopsychosozial Health* *Ludwig-Maximilian-University, Munich, Germany*
Alarcos Cieza	*Psychologist* *Steering Committee member of the ICF Research Branch* *Institute for Health and Rehabilitation Sciences (IHRS)* *Unit for Biopsychosozial Health* *Ludwig-Maximilian-University, Munich, Germany*
Heinrich Gall	*Physicist* *Institute for Health and Rehabilitation Sciences (IHRS)* *Unit for Biopsychosozial Health* *Ludwig-Maximilian-University, Munich, Germany*
Melissa Selb	*Vocational Counselor* *Coordinator of the ICF Research Branch* *Swiss Paraplegic Research (SPF), Nottwil, Switzerland*

Candidate ICF categories – Individual Vote

Bipolar Disorder - Individual Vote

ICF code level			ICF title	Vote !
2nd	3rd	4th		if yes ✓
b110			Consciousness functions	
+b114			Orientation functions	
b114			Orientation functions	
	b1140		Orientation to time	
	b1141		Orientation to place	
	b1142		Orientation to person	
		b11420	Orientation to self	
		b11421	Orientation to others	
b117			Intellectual functions	
b122			Global psychosocial functions	
+b126			Temperament and personality functions	
b126			Temperament and personality functions	
	b1260		Extraversion	
	b1261		Agreeableness	
	b1262		Conscientiousness	
	b1263		Psychic stability	
	b1264		Openness to experience	
	b1265		Optimism	
	b1266		Confidence	
	b1267		Trustworthiness	
+b130			Energy and drive functions	
b130			Energy and drive functions	
	b1300		Energy level	
	b1301		Motivation	
	b1302		Appetite	
	b1303		Craving	
	b1304		Impulse control	
+b134			Sleep functions	
b134			Sleep functions	
	b1340		Amount of sleep	
	b1341		Onset of sleep	
	b1342		Maintenance of sleep	
	b1343		Quality of sleep	
	b1344		Functions involving the sleep cycle	
+b140			Attention functions	
b140			Attention functions	
	b1400		Sustaining attention	
	b1401		Shifting attention	
	b1402		Dividing attention	
	b1403		Sharing attention	
+b144			Memory functions	
b144			Memory functions	
	b1440		Short-term memory	
	b1441		Long-term memory	
	b1442		Retrieval of memory	
+b147			Psychomotor functions	
b147			Psychomotor functions	
	b1470		Psychomotor control	
	b1471		Quality of psychomotor functions	

Bipolar Disorder - Individual Vote

+b152			Emotional functions	
b152			Emotional functions	
	b1520		Appropriateness of emotion	
	b1521		Regulation of emotion	
	b1522		Range of emotion	
+b156			Perceptual functions	
b156			Perceptual functions	
	b1560		Auditory perception	
	b1561		Visual perception	
	b1562		Olfactory perception	
	b1563		Gustatory perception	
	b1564		Tactile perception	
	b1565		Visuospatial perception	
+b160			Thought functions	
b160			Thought functions	
	b1600		Pace of thought	
	b1601		Form of thought	
	b1602		Content of thought	
	b1603		Control of thought	
+b164			Higher-level cognitive functions	
b164			Higher-level cognitive functions	
	b1640		Abstraction	
	b1641		Organization and planning	
	b1642		Time management	
	b1643		Cognitive flexibility	
	b1644		Insight	
	b1645		Judgement	
	b1646		Problem-solving	
+b167			Mental functions of language	
b167			Mental functions of language	
	b1670		Reception of language	
		b16700	Reception of spoken language	
		b16701	Reception of written language	
		b16702	Reception of sign language	
	b1671		Expression of language	
		b16710	Expression of spoken language	
		b16711	Expression of written language	
		b16712	Expression of sign language	
	b1672		Integrative language functions	
+b172			Calculation functions	
b172			Calculation functions	
	b1720		Simple calculation	
	b1721		Complex calculation	
+b180			Experience of self and time functions	
b180			Experience of self and time functions	
	b1800		Experience of self	
	b1801		Body image	
	b1802		Experience of time	

Bipolar Disorder - Individual Vote

+b210			Seeing functions	
b210			Seeing functions	
	b2100		Visual acuity functions	
		b21000	Binocular acuity of distant vision	
		b21001	Monocular acuity of distant vision	
		b21002	Binocular acuity of near vision	
		b21003	Monocular acuity of near vision	
	b2101		Visual field functions	
	b2102		Quality of vision	
		b21020	Light sensitivity	
		b21021	Colour vision	
		b21022	Contrast sensitivity	
		b21023	Visual picture quality	
b230			Hearing functions	
b235			Vestibular functions	
+b240			Sensations associated with hearing and vestibular function	
b240			Sensations associated with hearing and vestibular function	
	b2400		Ringing in ears or tinnitus	
	b2401		Dizziness	
	b2402		Sensation of falling	
	b2403		Nausea associated with dizziness or vertigo	
	b2404		Irritation in the ear	
	b2405		Aural pressure	
b265			Touch function	
+b280			Sensation of pain	
b280			Sensation of pain	
	b2800		Generalized pain	
	b2801		Pain in body part	
		b28010	Pain in head and neck	
		b28011	Pain in chest	
		b28012	Pain in stomach or abdomen	
		b28013	Pain in back	
		b28014	Pain in upper limb	
		b28015	Pain in lower limb	
		b28016	Pain in joints	
	b2802		Pain in multiple body parts	
	b2803		Radiating pain in a dermatome	
	b2804		Radiating pain in a segment or region	
b310			Voice functions	
b320			Articulation functions	
+b330			Fluency and rhythm of speech functions	
b330			Fluency and rhythm of speech functions	
	b3300		Fluency of speech	
	b3301		Rhythm of speech	
	b3302		Speed of speech	
	b3303		Melody of speech	
b340			Alternative vocalization functions	
+b410			Heart functions	
b410			Heart functions	
	b4100		Heart rate	
	b4101		Heart rhythm	
	b4102		Contraction force of ventricular muscles	
	b4103		Blood supply to the heart	

Bipolar Disorder - Individual Vote

+b415			Blood vessel functions	
b415			Blood vessel functions	
	b4150		Functions of arteries	
	b4151		Functions of capillaries	
	b4152		Functions of veins	
+b420			Blood pressure functions	
b420			Blood pressure functions	
	b4200		Increased blood pressure	
	b4201		Decreased blood pressure	
	b4202		Maintenance of blood pressure	
+b430			Haematological system functions	
b430			Haematological system functions	
	b4300		Production of blood	
	b4301		Oxygen-carrying functions of the blood	
	b4302		Metabolite-carrying functions of the blood	
	b4303		Clotting functions	
+b435			Immunological system functions	
b435			Immunological system functions	
	b4350		Immune response	
		b43500	Specific immune response	
		b43501	Non-specific immune response	
	b4351		Hypersensitivity reactions	
	b4352		Functions of lymphatic vessels	
	b4353		Functions of lymph nodes	
b440			Respiration functions	
+b455			Exercise tolerance functions	
b455			Exercise tolerance functions	
	b4550		General physical endurance	
	b4551		Aerobic capacity	
	b4552		Fatiguability	
+b510			Ingestion functions	
b510			Ingestion functions	
	b5100		Sucking	
	b5101		Biting	
	b5102		Chewing	
	b5103		Manipulation of food in the mouth	
	b5104		Salivation	
	b5105		Swallowing	
		b51050	Oral swallowing	
		b51051	Pharyngeal swallowing	
		b51052	Oesophageal swallowing	
	b5106		Regurgitation and vomiting	
b515			Digestive functions	
b525			Defecation functions	
b530			Weight maintenance functions	
+b535			Sensations associated with the digestive system	
b535			Sensations associated with the digestive system	
	b5350		Sensation of nausea	
	b5351		Feeling bloated	
	b5352		Sensation of abdominal cramps	

Bipolar Disorder - Individual Vote

+b540			General metabolic functions	
b540			General metabolic functions	
	b5400		Basal metabolic rate	
	b5401		Carbohydrate metabolism	
	b5402		Protein metabolism	
	b5403		Fat metabolism	
+b545			Water, mineral and electrolyte balance functions	
b545			Water, mineral and electrolyte balance functions	
	b5450		Water balance	
		b54500	Water retention	
		b54501	Maintenance of water balance	
	b5451		Mineral balance	
	b5452		Electrolyte balance	
+b550			Thermoregulatory functions	
b550			Thermoregulatory functions	
	b5500		Body temperature	
	b5501		Maintenance of body temperature	
b555			Endocrine gland functions	
b610			Urinary excretory functions	
+b620			Urination functions	
b620			Urination functions	
	b6200		Urination	
	b6201		Frequency of urination	
	b6202		Urinary continence	
+b640			Sexual functions	
b640			Sexual functions	
	b6400		Functions of sexual arousal phase	
	b6401		Functions of sexual preparatory phase	
	b6402		Functions of orgasmic phase	
	b6403		Functions of sexual resolution phase	
b650			Menstruation functions	
+b660			Procreation functions	
b660			Procreation functions	
	b6600		Functions related to fertility	
	b6601		Functions related to pregnancy	
	b6602		Functions related to childbirth	
	b6603		Lactation	
+b670			Sensations associated with genital and reproductive functions	
b670			Sensations associated with genital and reproductive functions	
	b6700		Discomfort associated with sexual intercourse	
	b6701		Discomfort associated with the menstrual cycle	
	b6702		Discomfort associated with menopause	
b710			Mobility of joint functions	
b730			Muscle power functions	
+b735			Muscle tone functions	
b735			Muscle tone functions	
	b7350		Tone of isolated muscles and muscle groups	
	b7351		Tone of muscles of one limb	
	b7352		Tone of muscles of one side of body	
	b7353		Tone of muscles of lower half of body	
	b7354		Tone of muscles of all limbs	
	b7355		Tone of muscles of trunk	

Bipolar Disorder - Individual Vote

+b750			Motor reflex functions	
b750			Motor reflex functions	
	b7500		Stretch motor reflex	
	b7501		Reflexes generated by noxious stimuli	
	b7502		Reflexes generated by other exteroceptive stimuli	
b755			Involuntary movement reaction functions	
+b760			Control of voluntary movement functions	
b760			Control of voluntary movement functions	
	b7600		Control of simple voluntary movements	
	b7601		Control of complex voluntary movements	
	b7602		Coordination of voluntary movements	
	b7603		Supportive functions of arm or leg	
+b765			Involuntary movement functions	
b765			Involuntary movement functions	
	b7650		Involuntary contractions of muscles	
	b7651		Tremor	
	b7652		Tics and mannerisms	
	b7653		Stereotypies and motor perseveration	
b770			Gait pattern functions	
+b780			Sensations related to muscles and movement functions	
b780			Sensations related to muscles and movement functions	
	b7800		Sensation of muscle stiffness	
	b7801		Sensation of muscle spasm	
b810			Protective functions of the skin	
b840			Sensation related to the skin	
+s110			Structure of brain	
s110			Structure of brain	
	s1100		Structure of cortical lobes	
		s11000	Frontal lobe	
		s11001	Temporal lobe	
		s11002	Parietal lobe	
		s11003	Occipital lobe	
	s1101		Structure of midbrain	
	s1102		Structure of diencephalon	
	s1103		Basal ganglia and related structures	
	s1104		Structure of cerebellum	
	s1105		Structure of brain stem	
		s11050	Medulla oblongata	
		s11051	Pons	
	s1106		Structure of cranial nerves	
s120			Spinal cord and related structures	
s140			Structure of sympathetic nervous system	
s150			Structure of parasympathetic nervous system	
s210			Structure of eye socket	
s220			Structure of eyeball	
+s320			Structure of mouth	
s320			Structure of mouth	
	s3200		Teeth	
	s3201		Gums	
	s3202		Structure of palate	
		s32020	Hard palate	
		s32021	Soft palate	

Bipolar Disorder - Individual Vote

		s32041	Lower lip	

Bipolar Disorder - Individual Vote

+s410			Structure of cardiovascular system	
s410			Structure of cardiovascular system	
	s4100		Heart	
		s41000	Atria	
		s41001	Ventricles	
	s4101		Arteries	
	s4102		Veins	
	s4103		Capillaries	
s420			Structure of immune system	
s520			Structure of oesophagus	
s530			Structure of stomach	
+s540			Structure of intestine	
s540			Structure of intestine	
	s5400		Small intestine	
	s5401		Large intestine	
s550			Structure of pancreas	
s560			Structure of liver	
s570			Structure of gall bladder and ducts	
+s580			Structure of endocrine glands	
s580			Structure of endocrine glands	
	s5800		Pituitary gland	
	s5801		Thyroid gland	
	s5802		Parathyroid gland	
	s5803		Adrenal gland	
+s610			Structure of urinary system	
s610			Structure of urinary system	
	s6100		Kidney	
	s6101		Ureters	
	s6102		Urinary bladder	
	s6103		Urethra	
+s630			Structure of reproductive system	
s630			Structure of reproductive system	
	s6300		Ovaries	
	s6301		Structure of uterus	
		s63010	Body of uterus	
		s63011	Cervix	
		s63012	Fallopian tubes	
	s6302		Breast and nipple	
	s6303		Structure of vagina and external genitalia	
		s63030	Clitoris	
		s63031	Labia majora	
		s63032	Labia minora	
		s63033	Vaginal canal	
	s6304		Testes	
	s6305		Structure of the penis	
		s63050	Glans penis	
		s63051	Shaft of penis	
	s6306		Prostate	

Bipolar Disorder - Individual Vote

s710			Structure of head and neck region	
+s730			Structure of upper extremity	
s730			Structure of upper extremity	
	s7300		Structure of upper arm	
		s73000	Bones of upper arm	
		s73001	Elbow joint	
		s73002	Muscles of upper arm	
		s73003	Ligaments and fasciae of upper arm	
	s7301		Structure of forearm	
		s73010	Bones of forearm	
		s73011	Wrist joint	
		s73012	Muscles of forearm	
		s73013	Ligaments and fasciae of forearm	
	s7302		Structure of hand	
		s73020	Bones of hand	
		s73021	Joints of hand and fingers	
		s73022	Muscles of hand	
		s73023	Ligaments and fasciae of hand	
s740			Structure of pelvic region	
+s750			Structure of lower extremity	
s750			Structure of lower extremity	
	s7500		Structure of thigh	
		s75000	Bones of thigh	
		s75001	Hip joint	
		s75002	Muscles of thigh	
		s75003	Ligaments and fasciae of thigh	
	s7501		Structure of lower leg	
		s75010	Bones of lower leg	
		s75011	Knee joint	
		s75012	Muscles of lower leg	
		s75013	Ligaments and fasciae of lower leg	
	s7502		Structure of ankle and foot	
		s75020	Bones of ankle and foot	
		s75021	Ankle joint and joints of foot and toes	
		s75022	Muscles of ankle and foot	
		s75023	Ligaments and fasciae of ankle and foot	
+s760			Structure of trunk	
s760			Structure of trunk	
	s7600		Structure of vertebral column	
		s76000	Cervical vertebral column	
		s76001	Thoracic vertebral column	
		s76002	Lumbar vertebral column	
		s76003	Sacral vertebral column	
		s76004	Coccyx	
	s7601		Muscles of trunk	
	s7602		Ligaments and fasciae of trunk	
+s770			Additional musculoskeletal structures related to movement	
s770			Additional musculoskeletal structures related to movement	
	s7700		Bones	
	s7701		Joints	
	s7702		Muscles	
	s7703		Extra-articular ligaments, fasciae, extramuscular aponeuroses, retinacula, septa, bursae, unspecified	

Bipolar Disorder - Individual Vote

s810			Structure of areas of skin	
s840			Structure of hair	
d110			Watching	
d115			Listening	
d150			Learning to calculate	
+d155			Acquiring skills	
d155			Acquiring skills	
	d1550		Acquiring basic skills	
	d1551		Acquiring complex skills	
d160			Focusing attention	
d163			Thinking	
d166			Reading	
d175			Solving problems	
d177			Making decisions	
d210			Undertaking a single task	
+d220			Undertaking multiple tasks	
d220			Undertaking multiple tasks	
	d2200		Carrying out multiple tasks	
	d2201		Completing multiple tasks	
	d2202		Undertaking multiple tasks independently	
	d2203		Undertaking multiple tasks in a group	
+d230			Carrying out daily routine	
d230			Carrying out daily routine	
	d2301		Managing daily routine	
	d2302		Completing the daily routine	
	d2303		Managing one's own activity level	
+d240			Handling stress and other psychological demands	
d240			Handling stress and other psychological demands	
	d2400		Handling responsibilities	
	d2401		Handling stress	
	d2402		Handling crisis	
d310			Communicating with - receiving - spoken messages	
d315			Communicating with - receiving - nonverbal messages	
d330			Speaking	
d335			Producing nonverbal messages	
+d350			Conversation	
d350			Conversation	
	d3500		Starting a conversation	
	d3501		Sustaining a conversation	
	d3502		Ending a conversation	
	d3503		Conversing with one person	
	d3504		Conversing with many people	
+d355			Discussion	
d355			Discussion	
	d3550		Discussion with one person	
	d3551		Discussion with many people	
+d360			Using communication devices and techniques	
d360			Using communication devices and techniques	

Bipolar Disorder - Individual Vote

+d410			Changing basic body position	
d410			Changing basic body position	
	d4100		Lying down	
	d4101		Squatting	
	d4102		Kneeling	
	d4103		Sitting	
	d4104		Standing	
	d4105		Bending	
	d4106		Shifting the body's centre of gravity	
d430			Lifting and carrying objects	
d440			Fine hand use	
d445			Hand and arm use	
+d450			Walking	
d450			Walking	
	d4500		Walking short distances	
	d4501		Walking long distances	
	d4502		Walking on different surfaces	
	d4503		Walking around obstacles	
+d460			Moving around in different locations	
d460			Moving around in different locations	
	d4600		Moving around within the home	
	d4601		Moving around within buildings other than home	
	d4602		Moving around outside the home and other buildings	
d465			Moving around using equipment	
d470			Using transportation	
d475			Driving	
d510			Washing oneself	
+d520			Caring for body parts	
d520			Caring for body parts	
	d5200		Caring for skin	
	d5201		Caring for teeth	
	d5202		Caring for hair	
	d5203		Caring for fingernails	
	d5204		Caring for toenails	
+d540			Dressing	
d540			Dressing	
	d5400		Putting on clothes	
	d5401		Taking off clothes	
	d5402		Putting on footwear	
	d5403		Taking off footwear	
	d5404		Choosing appropriate clothing	
d550			Eating	
d560			Drinking	
+d570			Looking after one’s health	
d570			Looking after one’s health	
	d5700		Ensuring one’s physical comfort	
	d5701		Managing diet and fitness	
	d5702		Maintaining one's health	
d610			Acquiring a place to live	
+d620			Acquisition of goods and services	
d620			Acquisition of goods and services	

Bipolar Disorder - Individual Vote

d630			Preparing meals	
+d640			Doing housework	
d640			Doing housework	
	d6400		Washing and drying clothes and garments	
	d6401		Cleaning cooking area and utensils	
	d6402		Cleaning living area	
	d6403		Using household appliances	
	d6404		Storing daily necessities	
	d6405		Disposing of garbage	
d650			Caring for household objects	
d660			Assisting others	
+d710			Basic interpersonal interactions	
d710			Basic interpersonal interactions	
	d7100		Respect and warmth in relationships	
	d7101		Appreciation in relationships	
	d7102		Tolerance in relationships	
	d7103		Criticism in relationships	
	d7104		Social cues in relationships	
	d7105		Physical contact in relationships	
+d720			Complex interpersonal interactions	
d720			Complex interpersonal interactions	
	d7200		Forming relationships	
	d7201		Terminating relationships	
	d7202		Regulating behaviours within interactions	
	d7203		Interacting according to social rules	
	d7204		Maintaining social space	
d730			Relating with strangers	
d740			Formal relationships	
+d750			Informal social relationships	
d750			Informal social relationships	
	d7500		Informal relationships with friends	
	d7501		Informal relationships with neighbours	
	d7502		Informal relationships with acquaintances	
	d7503		Informal relationships with co-inhabitants	
	d7504		Informal relationships with peers	
+d760			Family relationships	
d760			Family relationships	
	d7600		Parent-child relationships	
	d7601		Child-parent relationships	
	d7602		Sibling relationships	
	d7603		Extended family relationships	
+d770			Intimate relationships	
d770			Intimate relationships	
	d7700		Romantic relationships	
	d7701		Spousal relationships	
	d7702		Sexual relationships	
d820			School education	
d825			Vocational training	
d830			Higher education	
+d845			Acquiring, keeping and terminating a job	
d845			Acquiring, keeping and terminating a job	
	d8450		Seeking employment	

Bipolar Disorder - Individual Vote

+d850			Remunerative employment	
d850			Remunerative employment	
	d8500		Self-employment	
	d8501		Part-time employment	
	d8502		Full-time employment	
d855			Non-remunerative employment	
d860			Basic economic transactions	
+d870			Economic self-sufficiency	
d870			Economic self-sufficiency	
	d8700		Personal economic resources	
	d8701		Public economic entitlements	
+d910			Community life	
d910			Community life	
	d9100		Informal associations	
	d9101		Formal associations	
	d9102		Ceremonies	
+d920			Recreation and leisure	
d920			Recreation and leisure	
	d9200		Play	
	d9201		Sports	
	d9202		Arts and culture	
	d9203		Crafts	
	d9204		Hobbies	
	d9205		Socializing	
+d930			Religion and spirituality	
d930			Religion and spirituality	
	d9300		Organized religion	
	d9301		Spirituality	
d940			Human rights	
d950			Political life and citizenship	
+e110			Products or substances for personal consumption	
e110			Products or substances for personal consumption	
	e1100		Food	
	e1101		Drugs	
e115			Products and technology for personal use in daily living	
e120			Products and technology for personal indoor and outdoor mobility and transportation	
+e125			Products and technology for communication	
e125			Products and technology for communication	
	e1250		General products and technology for communication	
	e1251		Assistive products and technology for communication	
+e130			Products and technology for education	
e130			Products and technology for education	
	e1300		General products and technology for education	
	e1301		Assistive products and technology for education	
e155			Design, construction and building products and technology of buildings for private use	
+e165			Assets	
e165			Assets	
	e1650		Financial assets	
	e1651		Tangible assets	
	e1652		Intangible assets	

Bipolar Disorder - Individual Vote

e210			Physical geography	
+e215			Population	
e215			Population	
	e2150		Demographic change	
	e2151		Population density	
+e225			Climate	
e225			Climate	
	e2250		Temperature	
	e2251		Humidity	
	e2252		Atmospheric pressure	
	e2253		Precipitation	
	e2254		Wind	
	e2255		Seasonal variation	
e240			Light	
+e250			Sound	
e250			Sound	
	e2500		Sound intensity	
	e2501		Sound quality	
e310			Immediate family	
e315			Extended family	
e320			Friends	
e325			Acquaintances, peers, colleagues, neighbours and community members	
e330			People in positions of authority	
e335			People in subordinate positions	
e340			Personal care providers and personal assistants	
e355			Health professionals	
e360			Other professionals	
e410			Individual attitudes of immediate family members	
e415			Individual attitudes of extended family members	
e420			Individual attitudes of friends	
e425			Individual attitudes of acquaintances, peers, colleagues, neighbours and community members	
e430			Individual attitudes of people in positions of authority	
e440			Individual attitudes of personal care providers and personal assistants	
e445			Individual attitudes of strangers	
e450			Individual attitudes of health professionals	
e455			Individual attitudes of health-related professionals	
e460			Societal attitudes	
e465			Social norms, practices and ideologies	
e525			Housing services, systems and policies	
+e535			Communication services, systems and policies	
e535			Communication services, systems and policies	
	e5350		Communication services	
	e5351		Communication systems	
	e5352		Communication policies	

Bipolar Disorder - Individual Vote

e550			Legal services, systems and policies	
+e555			Associations and organizational services, systems and policies	
e555			Associations and organizational services, systems and policies	
	e5550		Associations and organizational services	
	e5551		Associations and organizational systems	
	e5552		Associations and organizational policies	
+e560			Media services, systems and policies	
e560			Media services, systems and policies	
	e5600		Media services	
	e5601		Media systems	
	e5602		Media policies	
+e570			Social security services, systems and policies	
e570			Social security services, systems and policies	
	e5700		Social security services	
	e5701		Social security systems	
	e5702		Social security policies	
e575			General social support services, systems and policies	
+e580			Health services, systems and policies	
e580			Health services, systems and policies	
	e5800		Health services	
	e5801		Health systems	
	e5802		Health policies	
+e585			Education and training services, systems and policies	
e585			Education and training services, systems and policies	
	e5850		Education and training services	
	e5851		Education and training systems	
	e5852		Education and training policies	
+e590			Labour and employment services, systems and policies	
e590			Labour and employment services, systems and policies	
	e5900		Labour and employment services	
	e5901		Labour and employment systems	
	e5902		Labour and employment policies	

APPENDIX C:

ICF CORE SETS FOR DEPRESSION

Categories of the component *'body functions'*:

ICF Code		ICF Category Title
2nd Level	3rd Level	
b117		Intellectual functions
b126		Temperament and personality functions
	b1260	Extraversion
	b1261	Agreeableness
	b1262	Conscientiousness
	b1263	**Psychic stability**
	b1265	**Optimism**
	b1266	Confidence
b130		Energy and drive functions
	b1300	**Energy level**
	b1301	**Motivation**
	b1302	**Appetite**
	b1304	Impulse control
b134		Sleep functions
	b1340	Amount of sleep
	b1341	Onset of sleep
	b1342	Maintenance of sleep
	b1343	Quality of sleep
	b1344	Functions involving the sleep cycle
b140		**Attention functions**
b144		Memory functions
b147		**Psychomotor functions**
b152		Emotional functions
	b1520	Appropriateness of emotion
	b1521	**Regulation of emotion**
	b1522	**Range of emotion**
b160		Thought functions
	b1600	Pace of thought
	b1601	Form of thought
	b1602	Content of thought
	b1603	Control of thought
b164		Higher-level cognitive functions
	b1641	Organization and planning
	b1641	Organization and planning
	b1642	Time management
	b1644	Insight
	b1645	Judgement
b180		Experience of self and time functions
	b1800	Experience of self
	b1801	Body image
b280		Sensation of pain
b460		Sensations associated with cardiovascular and respiratory functions
b530		Weight maintenance functions
b535		Sensations associated with the digestive system
b640		Sexual functions
b780		Sensations related to muscles and movement functions

*Categories in **bold** belong to the Brief ICF Core Set for Depression.*

Categories of the component *'activities and participation':*

ICF Code		ICF Category Title
2nd Level	3rd Level	
d110		Watching
d115		Listening
d163		**Thinking**
d166		Reading
d175		**Solving problems**
d177		**Making decisions**
d210		Undertaking a single task
d220		Undertaking multiple tasks
d230		Carrying out daily routine
	d2301	**Managing daily routine**
	d2302	Completing the daily routine
	d2303	**Managing one's own activity level**
d240		**Handling stress and other psychological demands**
d310		Communicating with -- receiving -- spoken messages
d315		Communicating with -- receiving -- nonverbal messages
d330		Speaking
d335		Producing nonverbal messages
d350		**Conversation**
d355		Discussion
d470		Using transportation (car, bus, train, plane, etc.)
d475		Driving (riding bicycle and motorbike, driving car, riding animals, etc.)
d510		**Washing oneself**
d520		Caring for body parts
d540		Dressing
d550		Eating
d560		Drinking
d570		**Looking after one's health**
d620		Acquisition of goods and services
d630		Preparing meals
d640		Doing housework
d650		Caring for household objects
d660		Assisting others
d710		Basic interpersonal interactions
d720		Complex interpersonal interactions
d730		Relating with strangers
d750		Informal social relationships
d760		**Family relationships**
d770		**Intimate relationships**
d830		Higher education
d845		**Acquiring, keeping and terminating a job**
d850		Remunerative employment
d860		Basic economic transactions
d865		Complex economic transactions
d870		Economic self-sufficiency
d910		Community life
d920		Recreation and leisure
d930		Religion and spirituality
d950		Political life and citizenship

*Categories in **bold** belong to the Brief ICF Core Set for Depression.*

.

Categories of the component *'environmental factors'*:

ICF Code		ICF Category Title
2nd Level	3rd Level	
	e1101	**Drugs**
e165		Assets
e225		Climate
e240		Light
e245		Time-related changes
e250		Sound
e310		**Immediate family**
e320		**Friends**
e325		**Acquaintances, peers, colleagues, neighbours and community members**
e330		People in positions of authority
e340		Personal care providers and personal assistants
e355		**Health professionals**
e360		Health-related professionals
e410		**Individual attitudes of immediate family members**
e415		**Individual attitudes of extended family members**
e420		**Individual attitudes of friends**
e425		Individual attitudes of acquaintances, peers, colleagues, neighbours and community members
e430		Individual attitudes of people in positions of authority
e440		Individual attitudes of personal care providers and personal assistants
e450		**Individual attitudes of health professionals**
e455		Individual attitudes of health-related professionals
e460		Societal attitudes
e465		Social norms, practices and ideologies
e525		Housing services, systems and policies
e570		Social security services, systems and policies
e575		General social support services, systems and policies
e580		**Health services, systems and policies**
e590		Labour and employment services, systems and policies

*Categories in **bold** belong to the Brief ICF Core Set for Depression.*